

***Lumbar non-fusion
posterior
stabilisation
devices***

May 2007

MSAC application 1099

Assessment report

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The Medical Services Advisory Committee (MSAC) is an independent committee which has been established to provide advice to the 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.

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

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Executive summary

The procedure

Lumbar non-fusion posterior stabilisation devices are an alternative to decompression surgery or fusion surgery with/without decompression for the treatment of degenerative conditions of the spine (primarily involving radicular pain) that have failed to respond to conservative treatment.

There are a number of different non-fusion devices available but they all operate on the same biomechanical principle, that is to limit hyperextension of the vertebrae at the level where the implant is inserted and to unload the posterior elements. Non-fusion devices may be divided into two main groups—interspinous spacers and pedicle screw systems. Interspinous spacer devices are, as their name suggests, inserted between the spinous processes and have no rigid fixation to the vertebral pedicles. Four kinds of interspinous spacers are available in Australia: the **X STOP**, the **Wallis**, the **Coflex** and the **DIAM**. These devices are all essentially similar and it is the view of the Advisory Panel that data for one device can be reasonably extrapolated to the others. There is only one pedicle screw system available in Australia, the **Dynesys**. This device differs from the interspinous devices as it may provide more rigid stabilisation and requires a more extensive surgical procedure for its insertion. Although the Dynesys looks superficially similar to standard posterior fusion devices, the structures connecting the vertebral bodies to one another are flexible and are not intended to provide rigid stability.

Medical Services Advisory Committee – role and approach

The Medical Services Advisory Committee (MSAC) was established by the Australian Government to strengthen the role of evidence in health financing decisions in Australia. The MSAC advises the Minister for Health and Ageing 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. A team from Adelaide Health Technology Assessment, School of Population Health and Clinical Practice, at the University of Adelaide, were engaged to conduct a systematic review of the literature on lumbar non-fusion posterior stabilisation devices for the treatment of symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc and facet joint osteoarthritis (primarily with lumbar radicular compromise). Literature searches were conducted up until April 2006 from AustHealth, Cinahl, Cochrane Library, Current Contents, Embase, Pre-medline, ProceedingsFirst, Web of Science and EconLit. Studies that met pre-defined criteria were included to assess the safety and effectiveness of non-fusion devices. An advisory panel with expertise in this area then evaluated the evidence and provided advice to the MSAC.

The MSAC's assessment of lumbar non-fusion posterior stabilisation

Clinical need

The Australian prevalence of symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise) that fail to respond to conservative management was determined from the number of surgical procedures (decompression and/or fusion procedures) suitable for this population that were undertaken in 2005–06. There were 11,843 patients who underwent fusion and/or decompression procedures in 2005–06 that were reimbursed through the Medicare Benefits Schedule (MBS). Since it is estimated that 71 per cent of patients receive decompression and/or fusion surgery in the private hospital system, it is estimated that another 4,937 patients would undergo these procedures in public hospitals. Therefore, the best estimate of the prevalence of degenerative disorders of the lumbar spine failing to respond to conservative management is estimated to be 16,680 per year. While this would include patients who receive comparative procedures for indications not suitable for non-fusion devices, there would also be a small number of patients who currently do not undergo surgery, but who might be considered for non-fusion stabilisation.

Safety

There were 11 studies that provided information on the safety of non-fusion devices.

The Dynesys

The highest level of evidence on the Dynesys came from two historically controlled studies (level III-3 interventional evidence), with the addition of six case series (level IV interventional evidence). In total, there were 406 people who received one or more of the Dynesys devices.

The rate of complications varied largely between studies. Major adverse events such as malpositioning of screws and pedicle fractures occurred in a median of 5 per cent of patients who received the Dynesys. Minor adverse events associated with the Dynesys included dural lesions and superficial wound infections. Limited comparative evidence (two studies of level III-3 evidence) found similar rates of minor complications between the Dynesys and the comparative treatments—decompression with/without fusion surgery.

Loosening of interspinous pedicle screws in the Dynesys may require intervention. Loose screws were evident in up to 16.7 per cent of patients who received the Dynesys device. No studies were available to compare rates of screw loosening or breakage between the Dynesys pedicle screw system and pedicle screw systems associated with fusion surgery.

Blood loss appeared to be related to the complexity and invasiveness of the procedure. The Dynesys device is inserted via a more invasive procedure than a nucleotomy alone, and subsequently had a greater blood loss (level III-3 evidence). One study found that the insertion of the Dynesys resulted in slightly more blood loss than a fusion procedure, but in this study 25 per cent more screws were inserted with the Dynesys than with fusion.

Overall, the Dynesys appears to be safe, and was found to be as safe as decompression surgery alone or decompression surgery with fusion.

The Dynesys device is the most invasive of the lumbar non-fusion posterior stabilisation devices because of the insertion of pedicle screws. It is therefore thought that generalising the results of the safety of the Dynesys to the other devices would not result in any underestimation of the safety concerns.

The X STOP

Two studies were included that assessed the safety of the X STOP device (level IV evidence). Minor complications such as respiratory distress, wound swelling and pain occurred in up to 8 per cent of patients, and major complications such as malpositioned implants occurred in up to 3 per cent of patients. One death was reported that was potentially related to the surgery, caused by pulmonary oedema in a patient with a history of cardiovascular disease. The X STOP requires a less invasive procedure than either the Dynesys system or fusion surgery, and was associated with lower mean blood loss.

The Wallis

Only one study was included that provided information on the Wallis device (level III-2 evidence). Forty patients who received the Wallis device after a discectomy had a similar frequency of minor complications as a group of patients who received a discectomy alone.

Effectiveness

A total of 11 studies provided information on the effectiveness of non-fusion devices.

The Dynesys

Two average quality historically controlled studies (level III-3 evidence) compared decompression and the Dynesys against decompression alone, or decompression and fusion surgery.

One of the controlled studies reported that the Dynesys was as effective at reducing pain as decompression surgery alone. The other controlled study found that patients who received fusion surgery reported less pain after 14 months than patients who received the Dynesys but, due to the small sample size, the statistical significance of this difference was not calculated. Both the Dynesys and fusion (with prior decompression surgery) were effective at improving quality of life (short form – 36).

The two controlled studies found that the Dynesys was as effective as, or more effective than, decompression surgery with/without fusion surgery at improving patient assessed functioning. The functional status of patients prior to and after surgery was also determined in two uncontrolled studies (level IV evidence), both of which reported an improvement in functioning after insertion of the Dynesys.

Analgesic use may be a surrogate measure of pain, and thus was a secondary effectiveness outcome in this report. One uncontrolled case series (level IV evidence) found that significantly fewer analgesics were used after insertion of the Dynesys device than previously.

Hospital stay was found to be shorter for patients who received the Dynesys (19.3 days) than those who received fusion surgery (28.4 days) (level III-3 evidence). These figures

are unlikely to reflect Australian practice (where average length of stay for spinal fusion is 9.1 days).

The Advisory Panel agrees that non-fusion devices are of equal clinical effectiveness to decompression with or without fusion when used for specific conditions.

The X STOP

Lower level (IV) evidence found that the X STOP resulted in statistically significant improvements on all subscales of the SF-36, although the clinical relevance of these results is unclear. There was a clinically significant improvement in pain in 40–60 per cent of patients who received the X STOP, while functioning was significantly improved in 10–57 per cent of patients.

The Wallis

Level III-2 evidence found that the Wallis device resulted in a greater reduction in patient pain than discectomy alone, although it is unclear whether the difference was statistically or clinically significant. Patients receiving the Wallis also had more functional improvement than those only receiving discectomy (level III-2 evidence). Patients had the same rate of subsequent operations regardless of whether a discectomy occurred with or without a Wallis implant.

Economic evaluation

As the Advisory Panel determined that lumbar non-fusion posterior stabilisation devices were no worse than decompression and/or fusion surgery for the treatment of symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise) that fail to respond to conservative management, the incremental cost/saving of non-fusion devices were determined. Taking into account medical practitioner fees, theatre and hospital accommodation, and the cost of the prostheses, non-fusion devices were found to cost \$7,634 more per person than decompression surgery alone. However, the non-fusion devices were found to cost \$10,875 *less* per person than fusion surgery. When the incremental costs of non-fusion devices are weighted according to the expected usage, the average additional cost per patient is \$3,097.

The overall financial impact to the Commonwealth is estimated to be between an expenditure *saving* of \$318,072 and an *increase* in expenditure of \$36,417. The impact on the Australian healthcare system is estimated to be an increase in expenditure of between \$83,472 and \$3,802,267 per year.

Recommendations

The MSAC has considered safety, effectiveness and cost-effectiveness for a pedicle screw device (Dynesys) and interspinous spacer devices compared with laminectomy with and without conventional spinal fusion.

Pedicle screw device (Dynesys)

Based on the limited evidence available for this device, the MSAC finds that the Dynesys is:

- as safe as laminectomy with spinal fusion, noting that, although there appears to be less blood loss with the use of Dynesys, there is a slightly higher incidence of loosening of the pedicle screws;
- no more effective in selected cases than laminectomy and fusion, and requires almost the same surgical exposure; and
- less cost-effective than laminectomy without fusion, and as cost-effective as laminectomy and spinal fusion.

The MSAC recommends that there is insufficient evidence to recommend a change in public funding arrangements for Dynesys at this time.

Interspinous spacers (X STOP, Wallis, Coflex, DIAM)

Based on the limited evidence available for these devices, the MSAC finds that interspinous spacer devices:

- are as safe as the conventional operations (if the devices were placed without laminectomy, the risks and surgical exposure would be less than for conventional laminectomy);
- may be as effective in selected cases as laminectomy and fusion and may be associated with a better outcome in patients with limited or localised (single level) disc disease; and
- may be as cost-effective as laminectomy without fusion and more cost-effective than laminectomy and spinal fusion.

The MSAC recommends that there is insufficient evidence to recommend a change in the public funding arrangements for interspinous devices at this time.

The Minister for Health and Ageing accepted this recommendation on 20 May 2008.

Introduction

The Medical Services Advisory Committee (MSAC) has reviewed the use of lumbar non-fusion posterior stabilisation devices for patients with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise). The 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. The MSAC adopts an evidence-based approach to its assessments, based on reviews of the scientific literature and other information sources, including clinical expertise.

The MSAC's terms of reference and membership are at Appendix A. The 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.

Rationale for assessment

Applications have been made to the MSAC from the Spine Society of Australia, Medtronic Australasia and Zimmer Australia/New Zealand to have lumbar non-fusion posterior stabilisation devices, for the treatment of symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise), listed on the Medicare Benefits Schedule. In response, the Australian Government Department of Health and Ageing commissioned an independent evaluator to assess the safety, effectiveness and cost-effectiveness of these devices. Lumbar non-fusion posterior stabilisation has been performed in Australia since 2002.

Background

Anatomy of the spine

The spinal column consists of 33 individual bones called vertebrae and these are divided into five sections: cervical, thoracic, lumbar, sacral and coccygeal vertebrae. The normal anatomy of the human spine consists of seven cervical, 12 thoracic, five lumbar, five sacral and four coccygeal vertebrae. The five sacral vertebrae are fused into one bone known as the sacrum. The coccygeal vertebrae are also fused into the one bone known as the coccyx (see Figure 1). Representation of each vertebra is in relation to its position in each section, such as L1 to L5 for the five lumbar vertebrae.

The intervertebral discs act as shock absorbers for the vertebrae, allowing motion to occur between them. The discs are made up of a hard outer layer called the annulus fibrosus which surrounds the soft nucleus or nucleus pulposus. Separation between the vertebral bodies is maintained by the height of the disc, which also allows the segmental nerve roots to exit without compression.

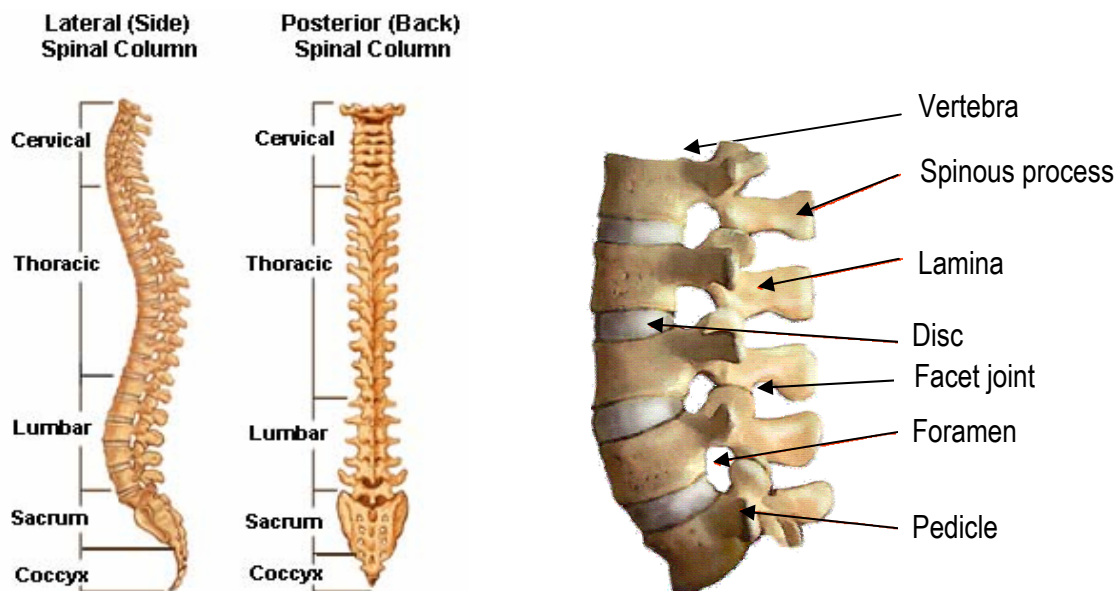


Figure 1 Anatomy of the spine and lumbar spine

Adapted from <<http://www.spineuniverse.com/displayarticle.php/article1394.html>> and <<http://www.spinalneurosurgery.com/lumbar%20anatomy.htm>>

Degenerative conditions of the lumbar spine

Degeneration (deterioration) is caused by daily wear and tear on the different structures of the spine, particularly the intervertebral discs. Pain may occur as a result of this deterioration, and is primarily treated by conservative management (such as analgesics and back bracing). When conservative management fails, surgery on the lumbar spine is considered for radicular pain (pain that radiates down the leg, groin and buttocks, with or without back pain, due to compression of the nerve roots) caused by degeneration of the spine.

In young and middle-aged adults (20–60 years old), radicular pain is usually caused by lumbar herniated discs or isthmic spondylolisthesis. Facet joint osteoarthritis, lumbar spinal stenosis and degenerative spondylolisthesis are the main causes of radicular pain in older adults (over 60 years of age) (Ullrich 1999). The following gives a brief description of each of these degenerative conditions of the lumbar spine.

Lumbar herniated disc

A prolapsed disc occurs when the disc is displaced, herniated or bulging from its normal position within the spinal column. The disc may place pressure on the nerve root and cause symptoms such as radiating pain, numbness, tingling and weakness (Braunwald et al 2001; Kasper et al 2005). The term radiculopathy may be defined as compression of a radicular nerve (nerve root) by a prolapsed (displaced) disc that may cause a very sharp pain that radiates from the spine to the limb (ie the neck, arm, lower back or leg). Surgery would be considered for a recurrent or large herniation with an extensive discectomy.

Facet joint osteoarthritis

Although the most common cause of low back pain is disc degeneration, if the mechanical integrity of the disc fails, this inevitably leads to degeneration of the facet joints. Although the reverse may not necessarily be true, facet joint osteoarthritis is one of the many causes of low back pain.

Spondylolysis and spondylolisthesis

Spondylolisthesis is a forward slip of one vertebral body over the one below. (Ullrich 1999). Of the many causes of this condition, the two that are relevant for treatment by non-fusion devices are:

1. **Degenerative spondylolisthesis**, which is due to degeneration of the motion segment (disc and facet joints) and is most commonly found at the L4–L5 segment due to its considerable flexion–extension movement (Braunwald et al 2001). The slip occurs because of loss of integrity of the disc and bony remodelling of the facet joints, and these factors occurring together can cause spinal stenosis.
2. **Isthmic spondylolisthesis**, which is a developmental condition due to a spondylolysis or defect in the *pars interarticularis* (which literally means the ‘piece between the articulations’) and is most commonly found at the L5–S1 segment (the junction of the lumbar spine and the sacrum). The slip occurs because the spondylolysis results in the vertebral body being dissociated from its posterior elements (laminae and spinous process). As a result, while the Dynesys (which attaches to the body via the pedicles) may be used in isthmic spondylolisthesis, this condition is unsuitable for interspinous devices.

Lumbar spinal stenosis

Lumbar spinal stenosis (LSS) is a narrowing of the spinal canal, often secondary to degenerative changes in the disc and the adjoining facet joint. This narrowing may limit the blood supply and venous drainage, affecting the nerve roots. The proposed pathological mechanism for radicular pain is thought to be one of ischaemia analogous with the vascular claudication of the lower limbs. Activity increases the blood supply with possible functional and postural changes in cross-section area of the spine, with the potential to reduce the volume of the spinal canal. The net result is a compartment

syndrome, where the pressures within the spinal canal begin to exceed the venous and arterial pressures in the vessels of the nerve roots. This leads to a functional ischaemia which gives rise to conduction defects in the nerve root. Hence the radicular pain and, in more serious cases, true neurological deficit (Keller 1999; Christie et al 2005). Spinal stenosis may be asymptomatic but in symptomatic patients it can result in neurogenic intermittent claudication (pain initiated by standing and increased with walking). Although not all symptomatic LSS leads to neurogenic intermittent claudication, its characteristic symptoms include back and leg pain, tingling, numbness and weakness.

Surgical treatments for the degenerative lumbar spine

Patients only become candidates for surgical treatment when they have exhausted non-operative treatments without pain relief (Gardner & Pande 2002). Surgery is suitable for a small number of patients who are psychologically healthy and who have the source of their pain verified through the use of clinical assessment, plain radiography, magnetic resonance imaging and discography where appropriate (Gardner & Pande 2002). Surgical options currently available for treating symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with radicular pain) include spinal decompression or fusion surgery with/without decompression.

Decompression surgery

The aim of decompression is to alleviate pain caused by compression of a nerve. The procedure involves removal of a portion of bone over the nerve root and/or disc material under the nerve root to provide more space for the nerve.

In a laminectomy, a 5–15-cm incision is made in the back, and the muscles are dissected off the lamina. The lamina is then removed and the facet joints are trimmed to create more room for the nerve roots (Ullrich 1999).

For compression of a nerve by a disc, microdiscectomy may be considered to alleviate symptoms. This involves a small (approximately 3 cm) incision in the midline of the low back. The back muscles are moved to allow the surgeon access to the nerve (possibly with the removal of some facet joint). The nerve root is then moved to the side and the disc material is removed. Almost all of the joints, muscles and ligaments are left intact (Adelaide Spine Clinic 2005).

Fusion surgery

The aim of fusion surgery is to use a bone graft to fuse the vertebrae superior and inferior to a disc. Bone grafts can be either autologous (harvested from the patient's own pelvic bone) or an allograft (from a bone bank) (Ullrich 1999). Recently, bone morphogenetic protein products have also been used. There are a number of different methods of performing fusion surgery, including anterior or posterior lumbar intervertebral body fusion and posterolateral fusion. Instrumentation is used to facilitate the fusion by providing stability (Spinasant 2000). There are three types of spinal instrumentation: pedicle screws, anterior interbody cages and posterior lumbar cages (Ullrich 1999).

Decompression and fusion surgery

For spines with segmental instability or potential post-operative instability after decompression, fusion surgery may be used in addition to decompression.

Procedure under review

Lumbar non-fusion posterior stabilisation devices

Non-fusion devices with/without decompression surgery are an alternative to either decompression surgery or fusion surgery with/without decompression for the treatment of primarily radicular pain associated with degenerative spine disorders once conservative treatment has failed. Non-fusion devices protect the spine and make use of materials to stabilise the affected spinal region, although the spinal region is still kept mobile. The aim of 'soft' or 'dynamic' stabilisation is to redistribute the transmission of spinal load and control any abnormal movement of the spinal segment (Sengupta 2004).

There are a number of dynamic non-fusion devices that use essentially the same biomechanical principles (Sengupta 2004). Those that were included in the current review are given in Table 1.

Table 1 Therapeutic Goods Administration approved lumbar non-fusion posterior stabilisation devices

Name	ARTG number
Wallis system (manufactured by Spine Next and distributed in Australia by Orthotech)	82909
X STOP (manufactured by St Francis Medical and distributed in Australia by Global Manufacturing Technology)	112448
Device for Intervertebral Assisted Motion (DIAM, previously known as the Minns silicone distraction device, manufactured by Cousin Biotech and marketed by Medtronic Australia)	100643
Coflex™ (previously known as the Interspinous U or Fixano U, manufactured by Fixano S.A. and distributed in Australia by Taylor Bryant)	119363
Dynesys device (Zimmer Spine)	100337

To date there are four known non-fusion devices that distract the interspinous processes, by positioning a spacer between them, to limit extension and unload the posterior spinal elements. These are the X STOP system, Wallis system, Coflex™ and Device for Intervertebral Assisted Motion (DIAM).

Their beneficial effects are created by reducing pressure on the posterior joints, reducing hyperlordosis (exaggerated lumbar curve), restricting mobility and opening up the foramina (Viscogliosi et al 2004). They are firmly attached between two adjacent spinous processes, thus avoiding the possibility of the device loosening from the spinal segment (Sengupta 2004). The implant is commonly inserted during a discectomy and/or decompression procedure (Spine Next 2005) but, in selected cases, it may be inserted as a primary method of treatment or adjacent to a level of fusion. Interspinous spacer non-fusion devices are designed to be implanted at levels L1 to L5, and may also be used in some cases for the spinous processes between L5 and S1 (Viscogliosi et al 2004).

Indications and contraindications for the interspinous non-fusion devices are provided in Table 2. The indications listed in Table 2 were derived from product information received from the applicants or from an industry analysis report (Viscogliosi et al 2004).

Table 2 Indications and contraindications for interspinous non-fusion devices

Indications	Contraindications
<ul style="list-style-type: none"> • Primary or recurrent disc herniation not responding to non-operative treatment • Degenerative spondylolisthesis with back pain and spinal stenosis/sciatica • Radiographically confirmed moderate or severe spinal stenosis, isolated to 1 or 2 levels, in a patient with or without concomitant low back pain • In association with surgical decompression of spinal and/or foraminal stenosis in the region of L1 to L5 • Adjacent to a level of fusion to reduce adjacent disc degeneration 	<ul style="list-style-type: none"> • Any medical or surgical condition precluding the potential benefit of spinal surgery • Acute or chronic systemic, spinal or localised infections • Systemic and metabolic diseases • Obesity • Pregnancy • Dependency on pharmaceutical drugs, drug abuse or alcoholism • Lack of patient cooperation • Foreign body sensitivity to the implant material • Scoliosis or kyphotic deformity • Significant osteopenia or osteoporosis

X STOP system

The X STOP Interspinous Process Distraction System was designed to treat patients with symptomatic lumbar spinal stenosis between L2 and L5 (St. Francis Medical Technologies 2002). The symptoms of lumbar spinal stenosis are generally intensified with lumbar extension (ie standing, walking) and are eased by flexion positions such as sitting or bending forwards (Zucherman et al 2005). The X STOP requires minimal access surgery to fix the spacer between the spinous processes. This decompresses the nerve roots, reduces the neurogenic claudication and allows the patient to resume normal posture (St. Francis Medical Technologies 2002).



Figure 2 The X STOP Interspinous Process Distraction System

Available at: <http://www.spine-dr.com/site/surgery/surgery_x_stop_BISS.html>, accessed 16 January 2006

Wallis system

The Wallis system is an interspinous non-fusion device which was developed in 1986. It was originally constructed from titanium but, following a study during the mid 1990s, a second generation model was developed. The interspinous spacer is now made of PEEK (polyetheretherketone) material and is held in place with a polyester ligament (Dacron

tape) (Sengupta 2004). While there is limited information available on the second generation of Wallis device, it could be expected that the results of its use would be similar to the first generation device. The spacer is fixed in position by a ligament around the processes and the device then normalises the mechanical behaviour of the vertebrae (Viscogliosi et al 2004).

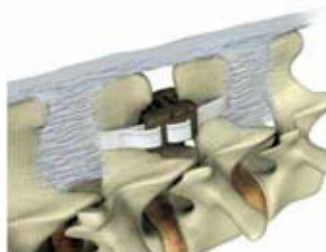


Figure 3 Wallis system

Available at: <<http://www.spine-health.com/research/trials/wallis/wallis.html>>, accessed 16 January, 2006

Coflex™ implant

The Coflex™ (previously known as the Fixano U or Interspinous U) was originally developed in 1994, and is a titanium device that is inserted between the spinous processes with wings that clamp onto the spinous processes (Kaech et al 2002; Spine Motion 2005).



Figure 4 Coflex interspinous implant

Available at: <http://www.ryortho.com/newsletters/05_16_05_Volume1_Issue12.pdf>, accessed 17 January 2006. Authorisation to use graphic given by Taylor Bryant Pty Ltd (pers. comm.)

Device for Intervertebral Assisted Motion

The Device for Intervertebral Assisted Motion (DIAM, previously known as the Minns silicone distraction device; Medtronic Australia) is registered for use in Australia by the Therapeutic Goods Administration and was launched in Europe in 2003. The DIAM is a silicon gel bag which is inserted between two spinous processes and fastened to the processes above and below the device by a ligament (Medtronic Sofamor Danek 2005). It is very similar to the Wallis device.



Figure 5 Device for Intervertebral Assisted Motion (DIAM)

Available at: <http://ruecken.qualimed.de/Diam_ein_neues_verfahren.html>, accessed 10 February 2006

The second major type of lumbar non-fusion posterior stabilisation device has some similarities to standard rigid fusion devices through the use of pedicle screw systems. The most common of these systems is the Dynamic neutralisation system (Dynesys Spinal System). Relatively more surgical exposure is required to obtain access for the pedicular screw attachment.

Dynesys

The Dynesys was developed in 1994 and comprises three elements: the pedicle screws, the spacers and a cord. Unlike the interspinous spacer non-fusion devices, there is no reliance on fixation between the spinous processes. Therefore, the Dynesys is indicated for isthmic spondylolisthesis. The titanium alloy screws anchor the neutralisation system to the vertebrae so as to maintain motion in any plane (Stoll et al 2002a). The spacers are used to restore disc height and the polycarbonate component of these spacers can be compressed, thereby allowing motion for extension and flexion. Lastly, the cord passing through the spacers also acts to control mobility of the segment (Zimmer 2005). Dynesys is used for treatment of lower back and leg pain caused by spinal stenosis, spondylolisthesis, radiculopathy or spondylarthrosis in up to five contiguous levels between L1 and S1 (Table 3) (Viscogliosi et al 2004). The main function of the Dynesys is to distribute the load across the processes and restore disc height (Grob et al 2005). The intention of the Dynesys is essentially to restabilise the spinal segment (Dubois 1999).



Figure 6 Dynesys stabilisation

Printed with permission from Zimmer Spine

Table 3 Indications and contraindications for the Dynesys (Viscogliosi et al 2004)

Indications	Contraindications
<ul style="list-style-type: none"> • Primary or recurrent disc herniation not responding to non-operative treatment • Isthmic spondylolisthesis with back pain and spinal stenosis/sciatica • Degenerative spondylolisthesis with back pain and spinal stenosis/sciatica • Radiographically confirmed moderate or severe spinal stenosis, isolated to 1 or 2 levels, in a patient with or without concomitant low back pain. • In association with surgical decompression of spinal and/or foraminal stenosis in the region of L1 to L5 • Spondylarthrosis + discopathy hyper-mobile and functional instability (pseudo-spondylolisthesis), potentially with mono- or multisegmental stenosis 	<ul style="list-style-type: none"> • Any medical or surgical condition precluding the potential benefit of spinal surgery • Acute or chronic systemic, spinal or localised infections • Systemic and metabolic diseases • Obesity • Pregnancy • Dependency on pharmaceutical drugs, drug abuse, or alcoholism • Lack of patient cooperation • Foreign body sensitivity to the implant material • Scoliosis or kyphotic deformity • Significant osteopenia or osteoporosis

Other relevant considerations

If they are used without other spinal surgical procedures, non-fusion devices have a possible advantage over conventional fusion surgery. The implants can be removed from the spine since they utilise a non-destructive procedure; thus, the anatomy remains the same after surgery.

Approach to assessment

Objective

To determine whether there is sufficient evidence, in relation to clinical need, safety, effectiveness and cost-effectiveness, to have lumbar non-fusion posterior stabilisation listed on the Medicare Benefits Schedule. Benefits are currently not payable under Medicare for these procedures.

Research questions

1. What is the prevalence in Australia of patients with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint arthritis (primarily with lumbar radicular compromise) failing to respond to conservative management?
2. Is lumbar non-fusion posterior stabilisation with/without decompression as safe as, or safer than, decompression or fusion with/without decompression?
3. Is lumbar non-fusion posterior stabilisation with/without decompression as effective as, or more effective than, decompression or fusion with/without decompression at providing relief from post-operative leg pain and/or preventing post-operative back pain or worsening of back pain, and improving the quality of life or functional status of patients, with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint arthritis (primarily with lumbar radicular compromise)?
4. Is lumbar non-fusion posterior stabilisation with/without decompression a cost-effective treatment option for patients with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint arthritis (primarily with lumbar radicular compromise) in comparison with fusion with/without decompression or decompression alone?

Expert advice

An advisory panel with expertise in orthopaedics, neurosurgery, rheumatology and consumer issues was established to evaluate the evidence from this Assessment Report and to provide advice to the MSAC from a clinical or consumer perspective. In selecting members for advisory panels, the MSAC's practice is to approach the appropriate medical colleges, specialist societies and associations, and consumer bodies for nominees. Membership of the advisory panel associated with this MSAC assessment is provided at Appendix B.

Review of literature

Literature sources and search strategies

The medical literature was searched to identify relevant studies concerning lumbar non-fusion posterior stabilisation devices for the period between 1994 and April 2006. The relevant lumbar non-fusion posterior stabilisation devices were first reported in English in 1994. Appendix C describes the electronic databases that were used for this search and other sources of evidence that were investigated. Grey literature was included in the search strategy. Unpublished literature, however, was not canvassed as it is difficult to

search for this literature exhaustively and systematically, and trials that are difficult to locate are often smaller and of lower methodological quality (Egger et al 2003). It is, however, possible that these unpublished data could impact on the results of this assessment. The literature received from the applicants was evaluated in the systematic review.

The search terms, presented in Appendix C, were used to identify literature in electronic bibliographic databases on the safety, effectiveness and cost-effectiveness of using lumbar non-fusion posterior stabilisation devices for patients with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with radicular compromise) that has failed to respond to conservative management.

Inclusion/exclusion criteria

In general, studies were excluded if they:

- did not address the research question;
- did not provide information on the pre-specified target population;
- did not include one of the pre-specified interventions;
- did not compare results to the pre-specified comparator;
- did not address one of the pre-specified outcomes and/or provided inadequate data on these outcomes; or
- did not have the appropriate study design.

Where two (or more) papers reported on different aspects of the same study, such as the methodology in one and the findings in the other, they were treated as one study. Similarly, if the same data were duplicated in multiple articles, only results from the most comprehensive or most recent article were included.

The criteria for including studies relevant to each of the research questions posed in this assessment are provided in Box 1 to Box 3 in the results section of this report.

Search results

The process of study selection for this report went through seven phases:

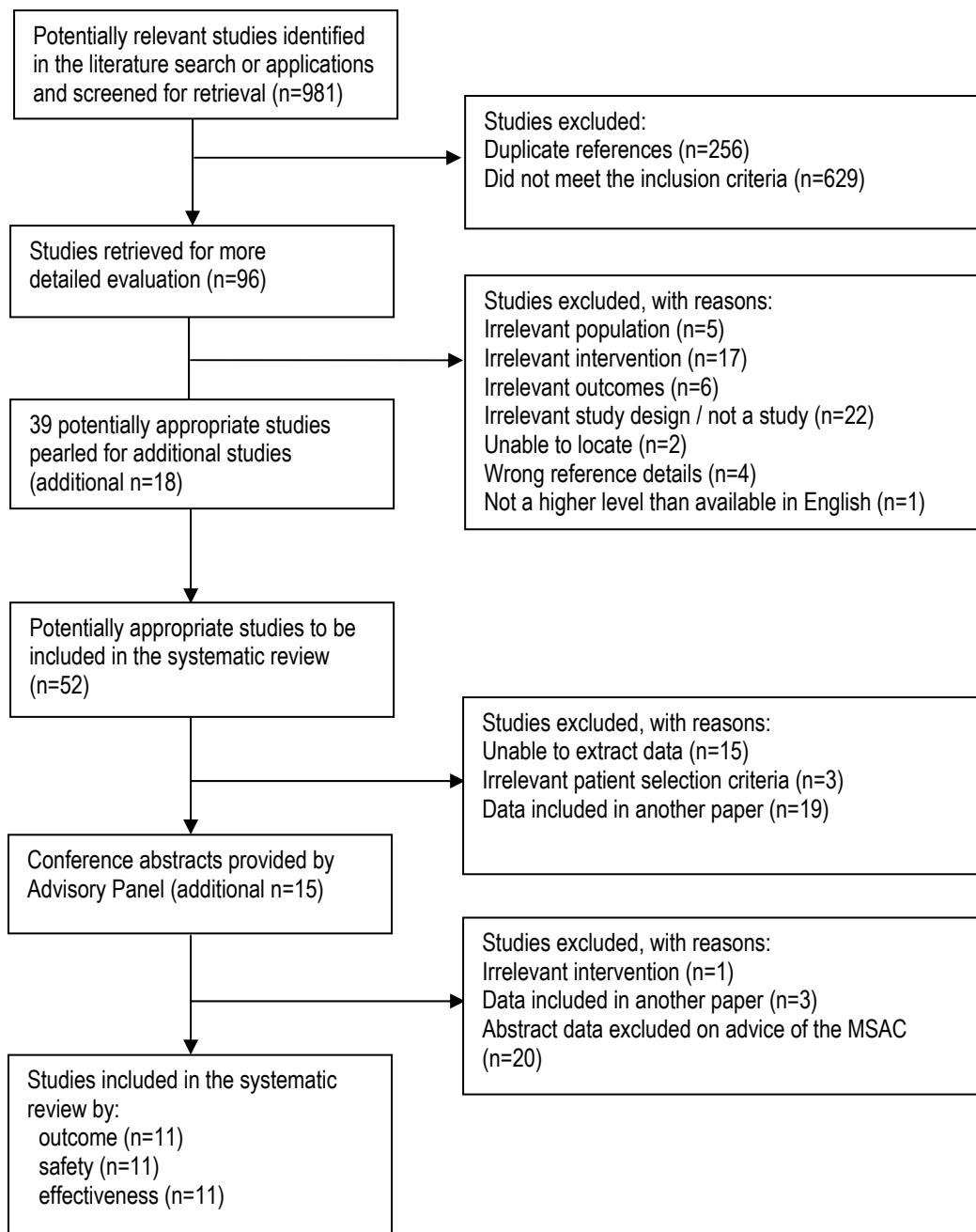
1. All reference citations from all literature sources were collated into an Endnote 8.0 database.
2. Duplicate references were removed.
3. Studies were excluded, on the basis of the complete citation information, if it was obvious that they did not meet the inclusion criteria. All other studies were retrieved for full-text assessment.

4. Inclusion criteria were independently applied to the full-text articles by one researcher and checked by another. Those articles meeting the criteria formed part of the evidence-base, and the remainder provided background information.
5. The reference lists of the included articles were pearled for additional relevant studies. These were retrieved and assessed according to phase 4.
6. The evidence-base consisted of articles from phases 4 and 5 that met the inclusion criteria.
7. Abstracts were removed on advice from the MSAC.

Any doubt concerning inclusions at phase 4 was resolved by group consensus. The results of the process of study selection—to collate the evidence base for assessing the safety and effectiveness of lumbar non-fusion posterior stabilisation devices—are provided in **Figure 7**.

Figure 7 Summary of the process used to identify and select studies for the assessment of safety and effectiveness of lumbar non-fusion posterior stabilisation devices

(adapted from Moher et al 1999)



Data extraction and analysis

A profile of key characteristics was developed for each included study (Appendix G). Studies that were unable to be retrieved or that met the inclusion criteria but contained insufficient or inadequate data for inclusion are provided in Appendix F. Definitions of all technical terms and abbreviations are provided in the Glossary.

Appraisal of the evidence

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 ^a
Quality	The methods used by investigators to minimise bias within a study design
Statistical precision	The <i>p</i> -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

^a See Table 5

Strength of the evidence

The three sub-domains (level, quality and statistical precision) are collectively a measure of the strength of the evidence.

Level

The designations of the levels of evidence are shown in Table 5.

Table 5 Designations of levels of evidence adapted from (NHMRC 2005)

Level	Intervention ^a
I ^b	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudorandomised controlled trial (ie alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> • non-randomised, experimental trial ^c • cohort study • case-control study • interrupted time series with a control group
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> • historical control study • two or more single arm study ^d • interrupted time series without a parallel control group
IV	Case series with either post-test or pre-test/post-test outcomes

^a Definitions of these study designs are provided in NHMRC 2000b; pp. 7–8.

^b A systematic review will only be assigned a level of evidence as high as the studies it contains, excepting where those studies are of level II evidence.

^c This also includes controlled before-and-after (pre-test/post-test) studies, as well as indirect comparisons (ie using A vs B and B vs C to determine A vs C).

^d Comparing single arm studies, ie case series from two studies

Note 1: Assessment of comparative harms/safety should occur according to the hierarchy presented for each of the research questions, with the proviso that this assessment occurs within the context of the topic being assessed. Some harms are rare and cannot feasibly be captured within randomised controlled trials; physical harms and psychological harms may need to be addressed by different study designs; harms from diagnostic testing include the likelihood of false positive and false negative results; harms from screening include the likelihood of false alarm and false reassurance results.

Note 2: When a level of evidence is attributed in the text of a document, it should also be framed according to its corresponding research question, eg level II intervention evidence; level IV diagnostic evidence; level III-2 prognostic evidence.

Quality

Studies providing information on the prevalence of lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with symptomatic lumbar radicular compromise) that has not responded to conservative management was not critically appraised as no intervention or association was being tested.

The appraisal of intervention studies pertaining to treatment effectiveness was undertaken using a checklist developed by Downs & Black (1998). This checklist is suitable for trials and cohort studies, and has been psychometrically assessed to have overall high internal consistency, good test–re-test and inter-rater reliability, and high criterion validity (Downs & Black 1998). The modified checklist produced an overall Quality Index score (total = 27), along with subscale scores (Reporting, External Validity, Bias and Confounding). Information on specific methodological components shown empirically to impact on treatment effect sizes were also included in this checklist—specifically, concealment of allocation, blinding and completeness of data (Schulz et al 1995; Moher et al 1998; Juni et al 2001).

Uncontrolled before-and-after case series are a poorer level of evidence for the assessment of effectiveness. The quality of this type of study design was assessed according to a checklist developed by the West Midlands Development and Evaluation Committee (Young & Ward 1999). A maximum quality score of 3 can be achieved.

Study quality was, however, presented in the assessment report in terms of the components of quality (eg selection bias, misclassification bias, reviewer bias), as well as the overall quality score.

Statistical precision

Statistical precision was determined using statistical principles. Small confidence intervals and p-values give an indication as to the probability that the reported effect is real and not attributable to chance (NHMRC 2000).

Size of effect

For intervention studies on lumbar non-fusion posterior stabilisation it was important to assess whether statistically significant differences are also clinically important. The size of the effect needed to be determined, as well as whether the 95% confidence interval includes only clinically important effects. Rank scoring methods were used to determine the clinically important benefit of the effect size in studies, as well as the clinical relevance of the evidence in controlled studies (NHMRC 2000).

Relevance of evidence

Similarly, the outcome being measured should be appropriate and clinically relevant. Inadequately validated (predictive) surrogate measures of a clinically relevant outcome should be avoided (NHMRC 2000). When assessing the safety and effectiveness of lumbar non-fusion posterior stabilisation, rank scoring methods were used to determine the clinical relevance of the outcome being assessed in any controlled studies (NHMRC 2000).

The body of evidence

Appraisal of the body of evidence was conducted along the lines suggested by the NHMRC in their guidance on clinical practice guideline development (NHMRC 2005). Five components are considered essential by the NHMRC when judging the body of evidence:

- The volume of evidence—which includes the number of studies sorted by their methodological quality and relevance to patients;
- The consistency of the study results—whether the better quality studies had results of a similar magnitude and in the same direction, ie homogenous or heterogenous findings;
- The potential clinical impact—appraisal of the precision, size and clinical importance or relevance of the primary outcomes used to determine the safety and effectiveness of the test;
- The generalisability of the evidence to the target population; and
- The applicability of the evidence—integration of this evidence for conclusions about the net clinical benefit of the intervention in the context of Australian clinical practice.

A matrix for assessing the body of evidence for each research question, according to the components above, was adapted for this assessment (Table 6) (NHMRC 2005).

Table 6 Body of evidence assessment matrix

Component	A Excellent	B Good	C Satisfactory	D Poor
Volume of evidence	Several level I or II studies with low risk of bias	One or two level II studies with low risk of bias or a SR/multiple level III study with low risk of bias	Level III studies with low risk of bias, or level I or II studies with moderate risk of bias	Level IV studies, or level I to III studies with high risk of bias
Consistency	All studies consistent	Most studies consistent and inconsistency may be explained	Some inconsistency reflecting genuine uncertainty around clinical question	Evidence is inconsistent
Clinical impact	Very large	Substantial	Moderate	Slight or restricted
Generalisability	Population(s) studied in body of evidence is/are the same as the target population	Population(s) studied in the body of evidence is/are similar to the target population	Population(s) studied in body of evidence is/are different to target population but it is clinically sensible to apply this evidence to target population	Population(s) studied in body of evidence is/are different to target population and it is hard to judge whether it is sensible to generalise to target population
Applicability	Directly applicable to Australian healthcare context	Applicable to Australian healthcare context with few caveats	Probably applicable to Australian healthcare context with some caveats	Not applicable to Australian healthcare context

Results of assessment

Burden of disease

Box 1 Study selection criteria to determine the burden of disease

Research question	
(1) What is the prevalence in Australia of symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise) that fails to respond to conservative management?	
Selection criteria	Inclusion criteria
Population	People with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise) in (1) Australia or, if this information is unavailable, (2) Western countries of similar demographic composition
Outcome	Prevalence—the proportion of people at a point in time with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise) who have failed to respond to conservative medical management ^a
Study design	Cross-sectional studies
Search period	In order to obtain relatively recent prevalence estimates, studies published before 1996 were not included
Language	Studies relevant to Australia's demographic composition are most likely to be published in English. Therefore, studies in languages other than English were not included

^a 1st line treatment

Degenerative conditions of the lumbar spine are significant contributors to illness, pain and disability. This becomes a burden not only to the individual both in terms of functional status and quality of life, but also to the community as a consequence of hospital and primary care service usage and, ultimately, on health system expenditure. Such degenerative conditions appear to increase with age as a result of deterioration of the segments constituting the spinal column. In Australia, there were 9,969 hospital separations in 2003–04 due to lumbar and other intervertebral disc disorders with radiculopathy (AIHW 2005).

Assessing the prevalence of symptomatic lumbar radicular compromise for this systematic review indicates the degree to which degenerative conditions of the lumbar spine are a burden in Australia. To determine the prevalence of *symptomatic* lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise), estimates need to include both subjective self-reported data on the level of patient pain and objective data such as lumbar radiographs to identify the presence of the condition.

Prevalence of symptomatic lumbar radicular compromise

There is limited evidence, worldwide, on the prevalence of symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise) that fails to respond to conservative management. While there is a vast amount of data assessing the prevalence of lower back pain, evidence on radicular pain is lacking. In addition, much of the available prevalence data focuses on work-related musculoskeletal disorders such as in nursing staff and industrial workers rather than the general population.

Two studies were found that assess the prevalence of degenerative spondylolisthesis, one of the four indications included in this systematic review. Both studies were from the

same research group but the populations of interest differed between the studies. One study (Vogt et al 1998) focused on white women aged 65 years and older while the second study collected data on older African American women (Vogt et al 2003). The findings of the latter study will not be discussed here as the population is not representative of the Australian population.

The first study, conducted in the United States, was cross-sectional in design (Vogt et al 1998) and looked at the prevalence of degenerative spondylolisthesis, separated into antero- and retrolisthesis, among white women aged 65 years and older. A random sample (n = 788) was selected from 2,401 women enrolled in the Pittsburgh clinic taking part in the Multicenter Study of Osteoporotic Fractures (SOF). The study specifies that the women were considered symptomatic if they reported back pain in the lower lumbar region for some time during the previous year. No information on neurogenic claudication or sciatica was given in this group of women. The prevalence of anterolisthesis, defined as a slippage of 3 mm or more, was 28.9 per cent, and of retrolisthesis was 14.2 per cent. A more conservative definition, with a cut-off slippage of 5 mm, reduces the prevalence of anterolisthesis to 14.2 per cent and of retrolisthesis to 3.2 per cent. The study indicates that approximately one-third to one-half of the women reported having symptoms of lower back pain at least some of the time during the previous year. Nevertheless, it is not clear in this study whether the women had received conservative or medical management, or whether this successfully managed their pain. Therefore, there is no clear indication of the likely symptomatic population that may be considered for non-fusion stabilisation.

Prevalence of degenerative spondylolisthesis

The burden of disease in Australia from, specifically, symptomatic degenerative spondylolisthesis was estimated from one available study conducted in the United States (Vogt et al 1998). The prevalence of degenerative spondylolisthesis in men or women under 65 years, as well as for the three remaining indications for non-fusion stabilisation, could not be determined from a systematic review of the literature.

The one relevant study indicates an overall prevalence of degenerative spondylolisthesis to be 43.1 per cent, and between 14.3 per cent and 21.5 per cent in the symptomatic population, when the vertebral slippage is defined as 3 mm or more. A change in the cut-off to more than 5 mm reduces the prevalence rate to 17.4 per cent (anterolisthesis—14.2%, retrolisthesis—3.2%) and between 5.8 per cent and 8.7 per cent in the symptomatic population (Table 7).

Table 7 Prevalence of degenerative spondylolisthesis

Study	Country	Population	Prevalence
(Vogt et al 1998)	USA	Cross-sectional study of women aged 65 years and over	<p>Symptomatic and asymptomatic</p> <p><i>3 mm cut-off</i></p> <p>Anterolisthesis: 28.9%</p> <p>Retrolisthesis: 14.2%</p> <p>Total: 43.1%</p> <p><i>5 mm cut-off:</i></p> <p>Anterolisthesis: 14.2%</p> <p>Retrolisthesis: 3.2%</p> <p>Total: 17.4%</p> <p>Symptomatic</p> <p><i>3 mm cut-off</i></p> <p>Total: 14.3–21.5%</p> <p><i>5 mm cut-off</i></p> <p>Total: 5.8–8.7%</p>

In order to apply these estimates of symptomatic degenerative spondylolisthesis to Australia, estimates for the total Australian female population 65 years and older are required. There was an estimated population of 1,469,136 females aged 65 years or older in 2005 (AIHW 2005). Based on the estimated symptomatic prevalence rate of 5.8–8.7 per cent (using a vertebral slippage cut-off of 5 mm), there are approximately 85,209 to 127,814 cases of symptomatic degenerative spondylolisthesis per year in Australia. The 5 mm cut-off was chosen because it correlates with the definition of vertebral slippage in Australia. However, the proportion of patients who would then go on for surgical treatment is far smaller, with evidence suggesting that 10–15 per cent of patients cannot be treated conservatively and require surgical treatment due to back or radicular pain (Frymoyer 1994; Matsunaga et al 2000). Based on 10–15 per cent of 85,209 to 127,814 cases, an estimated 8,521 to 19,172 symptomatic women (over the age of 65 years) are likely to have symptomatic spondylolisthesis that is unresponsive to conservative treatment and need to undergo surgery.

Determining the usage of items on the Medicare Benefit Schedule (MBS) enabled identification of the number of hospital separations in private hospitals in Australia in 2005–06 that were relevant to this symptomatic population requiring surgery (Medicare Australia 2006). An upper estimate (and overestimate) was identified as the total number of hospital separations for decompression or fusion. This includes surgery for indications where non-fusion stabilisation would be inappropriate.

A total of 6,883 hospital separations in 6,875 patients in private hospitals were identified for the most common decompression procedures relevant to non-fusion stabilisation. These included laminectomy for recurrent disc lesion or spinal stenosis, involving one level (item no. 40303) and laminectomy for spinal stenosis involving more than one level (item no. 40306). A total of 3,319 posterior fusion procedures were identified in 2,691 patients. These included posterior bone graft (item no. 48642 and 48645), postero-lateral bone graft (items 48648 and 48651) and posterior inter-body fusion (items 48654 and 48657). There were 1,907 patients who received both decompression and fusion surgery. Therefore, 4,968 patients received decompression surgery without fusion surgery. Of these, 1,996 patients received decompression at a single level and 2,972 at multiple levels (Statistics section, Department of Health and Ageing, Australian Government).

Therefore, the total number of patients who received decompression procedures, or fusion procedures with or without decompression, in 2005–06 that are relevant to non-fusion stabilisation was 11,843.

Australian Refined Diagnosis Related Group (AR-DRG) round 7 cost estimates suggest that the split between private and public patients for decompression and fusion surgery is 71 per cent to 29 per cent. Therefore, decompression or fusion with/without decompression appears to be responsible for an estimated 4,837 public hospital separations. This indicates that a total of 16,680 hospital separations for both comparative procedures are predicted across private and public hospitals.

Consequently, the estimated prevalence rate obtained from MBS data falls within the range obtained from the population-based study estimate determined from Vogt et al (1998). Although Vogt et al (1998) only considered one common indication, it appears considerably similar to the hospitalisation-based estimate from the MBS (Table 8).

Table 8 Summary table of estimated symptomatic patients unresponsive to treatment

Source of information	Prevalence
Population-based estimated (Vogt et al 1998)	8,521–19,172
Public and private patients undergoing common comparator procedures	16,680

Therefore, the best estimate of the number of symptomatic patients unresponsive to conservative treatment for lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with radicular compromise) is considered to be 16,680 per year in Australia. This estimate is based on figures which may include indications for surgery that are somewhat dissimilar to those required for non-fusion stabilisation. However, this would be counterbalanced by those patients currently indicated for, but not undergoing or choosing, surgery and who may choose to undergo the less invasive non-fusion stabilisation.

Safety of lumbar non-fusion posterior stabilisation

Lumbar non-fusion posterior stabilisation was assessed in terms of possible patient harms that may result from the procedure or device. Studies assessing this issue were assessed for inclusion in this report according to the criteria delineated *a priori* in Box 2.

Box 2 Study selection criteria to determine the safety of lumbar non-fusion posterior stabilisation

Research question	
Is lumbar non-fusion posterior stabilisation with/without decompression as safe as, or safer than, decompression or fusion with/without decompression surgery?	
Selection criteria	Inclusion criteria
Population	People with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise) who have failed to respond to conservative management
Intervention	Lumbar non-fusion posterior stabilisation devices with/without decompression (eg X STOP, Wallis system, Dynesys, DIAM, Coflex)
Comparators	1) Decompression surgery (eg laminectomy, discectomy) 2) Fusion surgery with/without decompression surgery (eg posterolateral gutter fusion, posterior lumbar interbody fusion, anterior lumbar interbody fusion, anterior/posterior spinal fusion)
Outcome	Primary—adverse physical health outcomes, including death, infection, haemorrhage, increased pain, neurological symptoms (eg numbness, tingling, paralysis), kyphosis, loss of lordosis, myocardial infarction, pulmonary embolism, deep vein thrombosis, infection, allergic reaction to implant, adjacent segment disease Secondary—device failure, device slip, device breakage, screw loosening
Study design	Randomised or non-randomised controlled trials, cohort studies, registers, case series, case reports or systematic reviews of these study designs
Search period	1994 – 4/2006 ^a
Language	Studies in languages other than English were only translated and included if they represented a higher level of evidence than that available in the English language evidence-base

^a Research reports on the clinical use of lumbar non-fusion posterior stabilisation devices were first published in 1994.

Eleven published studies met the inclusion criteria that reported on the safety of the Dynesys, X STOP and Wallis devices. Two studies assessing the DIAM were found that on initial assessment appeared to fit the inclusion criteria (Schivone & Pasquale 2003; Taylor et al, submitted), but on further advice from the Advisory Panel were excluded, as the patient selection criteria were inappropriate for the current review (Appendix F). Information on the Coflex and DIAM were available in abstract form, but on advice from the MSAC were removed from this Report. Therefore, no published studies were identified that allowed the extraction of safety information in the correct population for either the DIAM or the Coflex device. Results for the Dynesys, X STOP and Wallis devices are separated below.

It is acknowledged that the use of case series reports to gain an understanding of the safety of non-fusion devices may introduce bias into this report, as case series of the comparators (decompression surgery or fusion surgery with or without prior decompression surgery) were not assessed.

Safety of the Dynesys

Primary safety outcomes were divided into serious and minor adverse events (including both intra-operative and post-operative complications). Adverse events were classified as

serious if they were likely to require hospitalisation or further surgery. Reoperations at the index level were considered therapeutic failures, and were considered an effectiveness outcome unless the reoperation was due to infection.

Serious adverse events

There were no *controlled* studies identified that mentioned serious adverse events relating to lumbar non-fusion posterior stabilisation devices. A range of uncontrolled studies (level IV evidence) on the safety of non-fusion devices are presented in Table 9 in order of study quality and sample size. All serious adverse events noted in the research papers have been included regardless of whether they appear to be caused by the device, surgery or pre-existing conditions. Common adverse events included pedicle fractures, which were also found through radiography and have been detailed under secondary safety outcomes.

There was a large variation in the types of complication associated with non-fusion devices. Six uncontrolled before-and-after case series (level IV interventional evidence) assessed the safety of the Dynesys device, and found serious adverse event rates between 2.9 and 25.8 per cent of patients. It is unclear whether the differences observed in the complication rates is true variance or a product of varying ways of defining complications and adverse events.

The rate of complications found from implanting the Dynesys is consistent with the data relating to the use of pedicle screws for spinal fusion.

Table 9 Serious complications after the Dynesys^a

Study	Level and quality	Population	Complications ^b
(Dubois et al 1999)	Level IV: Uncontrolled before-and-after case series Quality: 3/3	57 patients	2/57 (3.5%) patients: 2 pedicle screws placed extrapedicularly resulting in neurologic symptoms
(Stoll et al 2002b)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	83 patients	3/83 (3.6%) patients: <i>Intra-operative or procedure related</i> 1 pedicle fracture (1.2%) 2 screw malplacements (1 of which required reoperation due to root compression signs) (2.4%) <i>Complications unrelated to implant</i> 1 dural lesion requiring reoperation 1 thromboembolism 1 cardiovascular problem 1 seroma which required draining 1 paresis which led to revision (later discovered to be due to non-Hodgkin lymphoma) 1 scar neuroma which was excised
(Schnake et al 2006)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	26 patients	3/26 (11.5%) patients: 1 death caused by unrelated pathology 1 osteoporotic L4 fracture and Dynesys removal 1 case of adjacent level instability
(Bordes-Monmeneu et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 2/3	94 patients	6/94 (6.4%) patients: <i>Intra-operative or procedure related</i> 1 case of malpositioning of screws (1.1%) 1 case of pedicle fracture (1.1%) <i>Further complications not due to technique</i> 2 cases of subcutaneous seroma (2.1%) 2 subclinical infections requiring removal of instrumented material (2.1%)
(Grob et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 1.5/3	31 patients	8/31 (25.8%) patients: <i>Intra-operative/immediately post-operative</i> 1 pleural effusion following allergic reaction to pain medication 1 case of post-operative cardiac insufficiency 1 dural tear requiring suturing and sealing with fibrinogenic material 1 case requiring morphine pump <i>Late complications</i> 1 system removed due to infection (after 8 months)
(Putzier et al 2004)	Level IV: Uncontrolled before-and-after case series Quality: 1/3	70 patients	2/70 (2.9%) patients: 1 newly developed radicular syndrome 1 progressive motor radicular syndrome

^a adverse events excluding those detected by radiograph, blood loss and minor adverse events, which are discussed separately; ^b likely to require hospitalisation or further surgery

Minor adverse events

Four comparative studies were included to provide information on the rate of adverse events (Table 10).

There were two medium-quality German historically controlled studies (level III-3 interventional evidence) performed in patients with spinal stenosis with degenerative

lumbar instability or symptomatic disc prolapse (Cakir et al 2003; Putzier et al 2005). These studies compared the rate of complications between the Dynesys system with decompression and decompression with or without fusion. No major adverse events were reported in either treatment group, and there was little difference in the rate of minor complications found between the treatment groups. The most common minor complications reported were dural lesions that occurred intra-operatively (without permanent post-operative symptoms) and superficial infections.

While slight differences were seen between the treatment groups, the studies were too small to determine whether the differences found were due to chance or real differences in the rate of adverse events. It is expected that the rate of adverse events after the Dynesys device would be similar to fusion surgery.

Table 10 Minor complications from the Dynesys (controlled studies)

Study	Level and quality ^a	Population	Complications		Risk Difference (95%CI)	Relative risk (95%CI)
			Dynesys + decompression	Decompression		
(Putzier et al 2005) Overlap of patients with (Putzier et al 2004)	Level III-3: Historical control study Quality: 19/27 Clin I: 4/4 R: 1/5	84 patients	Dynesys + decompression	Decompression	0.02 (-0.09, 0.14)	1.40 (0.30, 6.53)
			3/35 (8.6%) patients: 2 dural lesions 1 superficial wound healing disorder	3/49 (6.1%) patients: 3 dural lesions		
(Cakir et al 2003)	Level III-3: Historical control study Quality: 18/27 Clin I: 4/4 R: 1/5	20 patients	Dynesys + decompression	Fusion + decompression	-0.10 (-0.41, 0.21)	0.50 (0.05, 4.67)
			1/10 (10%) patients: 1 dural lesion No superficial or deep infection	2/10 (20%) patients: 1 dural lesion No superficial or deep infection 1 injury to vena iliaca		

^a See Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome).

Six further uncontrolled case series assessed minor complications after insertion of the Dynesys (Table 11). Minor complications such as dural lesions or superficial wound infections occurred in up to 7.7 per cent of patients.

Table 11 Minor complications from the Dynesys (uncontrolled studies)

Study	Level and quality	Population	Complications
(Dubois et al 1999)	Level IV: Uncontrolled before-and-after case series Quality: 3/3	57 patients	No complications related to material (pedicular screws, cords or spacers)
(Stoll et al 2002b)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	83 patients	3/83 (3.6%) patients: 1 case infection 1 hyperesthesia (resolving) 1 dural lesion not requiring reoperation
(Schnake et al 2006)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	26 patients	2/26 (7.7%) patients: 2 cases of transient leg paraesthesia
(Bordes-Monmeneu et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 2/3	94 patients	High percentage (frequency not stated) of post-operative unilateral or bilateral pain in femoral skin region, which disappeared spontaneously in 2–3 days Relatively frequent pains (frequency not stated) in sacroiliac region
(Grob et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 1.5/3	31 patients	2/31 (6.4%) patients: 1 case of post-operative mental confusion 1 case of infection
(Putzier et al 2004) overlap of patients with (Putzier et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 1/3	70 patients	3/70 (4.3%) patients: 2 dura leakages 1 superficial wound infection

Radiographic findings

Radiography is used to detect subsequent degeneration of the index vertebral segment and surrounding vertebral segments, malpositioned implants, and implants that have moved or broken, all of which may require intervention.

Two controlled studies reported their follow-up observations from radiography. One study compared the Dynesys device with fusion (both with prior decompression) (Cakir et al 2003) and found that no patients in either treatment group had any breakage or dislodgment of screws that could be detected by radiographic follow-up. One historically controlled study (level III-3 interventional evidence) found considerably fewer complications through radiography after the Dynesys plus decompression (nucleotomy) than after a nucleotomy alone (risk difference = -0.41 ; 95%CI $-0.55, -0.27$) (Table 12). This study found that there was significantly less progressive degeneration seen by radiography in patients who received instrumentation (Dynesys) than a nucleotomy alone for symptomatic disc prolapse with initial segmental degeneration after 24–47–months. It was concluded that, while a nucleotomy increases the probability of accelerated degeneration of the treated segment, the Dynesys could assist in preventing further disc degeneration (Putzier et al 2005).

Table 12 Radiographic observations after insertion of the Dynesys (controlled study)

Study	Level and quality ^a	Population	Radiographic observations		Risk Difference (95%CI)	Relative risk (95%CI)
(Putzier et al 2005) Overlap with (Putzier et al 2004)	Level III-3: Historical control study Quality: 19/27 Clin I: 1/4 R: 2/5	84 patients	Dynesys + nucleotomy	Nucleotomy	-0.41 (-0.55, -0.27)	Undefined
			0/35 (0.0%) patients: No loosening or breaking of screws No progressive height reduction, disc protrusion or prolapse No cases of progressive degeneration No stenosing osseous or ligamentous changes No new appearance or progression of spondylarthrosis	20/49 (40.8%) patients: 5 cases (10.2%) with <20% loss of height in intervertebral space 1 case re prolapse 8 patients (16.3%) with signs of progressive degeneration No stenosing osseous or ligamentous changes 6 cases of new or increasing signs of spondylarthrosis		

^a See Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome).

Five uncontrolled case series (level IV interventional evidence) were found that assessed patients with the Dynesys by radiographic means (Table 13). Device complications or further degeneration were evident in 3.5–16.7 per cent of patients. Loose screws or loosening of the device were the most common radiographic finding noted subsequent to the procedure. When these complications occurred, the device was frequently removed and revised to fusion (Table 31). It has been stated that the screw-loosening rate found with the Dynesys device is as low as, or lower than, rigid pedicle instrumentation (Stoll et al 2002b), but no direct comparative evidence was found to substantiate this claim.

Table 13 Radiographic observations after insertion of the Dynesys (uncontrolled studies)

Study	Level and quality	Population	Radiographic observations
(Dubois et al 1999)	Level IV: Uncontrolled before-and-after case series Quality: 3/3	57 patients	2/57 (3.5%) patients: 2 patients with protrusion of intervertebral disc in the adjacent level
(Stoll et al 2002b)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	83 patients	7/73 (9.5%) patients: 7 patients with screw loosening (10/280 screws (3.6%), 2 of which were confirmed and removed)
(Schnake et al 2006)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	24/26 patients	4/24 (16.7%) implant failures: 3 loose screws 1 patient with screw loosening and breakage 7 patients with signs of adjacent segment degeneration Progression of spondylolisthesis 2.1% No significant change in lordosis or intervertebral height
(Grob et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 1.5/3	31 patients	4/31 (12.9%) patients: 1 case where screws were positioned extrapedicularly 2 cases where screws were positioned too far laterally 1 case where screws on right-hand side showed loosening None of these cases caused significant symptoms or necessitated reintervention
(Putzier et al 2004) Overlap with (Putzier et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 1/3	70 patients	3/70 (4.3%) patients: 2 patients with screw loosening (6 screws; 2.8% of patients) 1 screw breakage

Blood loss

Two historically controlled studies (level III-3 evidence) compared the Dynesys system with decompression against either decompression alone or fusion with decompression (Table 14). Mean blood loss was less in the patient group who received decompression (nucleotomy) alone than in those patients who underwent decompression with the Dynesys. When decompression and Dynesys were compared against decompression and fusion, mean blood loss was lower in the group who received fusion surgery; however, 25 per cent more screws were used in the patients who received the Dynesys device (54 screws) than for the fusion procedures (42 screws) (Cakir et al 2003).

Table 14 Blood loss during the implantation of the Dynesys (controlled studies)

Study	Level and quality ^a	Population	Mean blood loss (range)	
			Decompression + Dynesys (n=35)	Decompression (n=49)
(Putzier et al 2005)	Level III-3: Historical control study Quality: 19/27 Clin I: 2/4 R: 2/5	84 patients	190 mL (80–440)	135 mL (40–380)
			Decompression + Dynesys (n=10)	Decompression + Fusion (n=10)
(Cakir et al 2003)	Level III-3: Historical control study Quality: 18/27 Clin I: 2/4 R: 2/5	20 patients	922 mL (300–3000)	892 mL (375–1600)

^a See Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance), and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome).

Two uncontrolled case series (level IV evidence) reported mean blood loss after insertion of the Dynesys (Table 15).

Table 15 Blood loss during the implantation of the Dynesys (uncontrolled studies)

Study	Level and quality	Population	Mean blood loss (range)
(Schnake et al 2006)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	26 patients	415 (100–700) mL
(Putzier et al 2004) Overlap with (Putzier et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 1/3	70 patients	220 (80–640) mL

Safety of the X STOP

The evidence base for assessing the safety of the X STOP consisted of two studies—one uncontrolled before-and-after case series, and a randomised controlled trial with one relevant arm of treatment (both level IV interventional evidence). These studies assessed the benefit of the X STOP in patients with neurogenic claudication secondary to lumbar spinal stenosis (Lee et al 2004; Zucherman et al 2005).

Primary safety outcomes

Primary safety outcomes were divided into serious and minor adverse events. Adverse events were classified as serious if they were likely to require hospitalisation or further surgery. Only one of the studies included on the X STOP device (level IV interventional evidence) mentioned serious complications (Zucherman et al 2005) (Table 16). One death was reported in the study, occurring in a patient with a history of cardiovascular disease after pulmonary oedema (Zucherman et al 2005). Another patient suffered a fall which dislodged the X STOP, which was subsequently removed without clinical sequelae.

Table 16 Serious complications from the X STOP ^a

Study	Level and quality	Population	Complications ^b
(Zucherman et al 2005)	Level IV: Single arm of randomised controlled trial Quality: 2.5/3	100 patients	3/100 (3.0%) patients: 1 case of pulmonary oedema 2 days after device implantation, resulting in death (in a patient with a history of cardiovascular disease) 1 implant dislodgement/migration requiring removal of implant 1 malpositioned implant No device-related intra-operative complications

^a adverse events excluding those detected by radiograph, blood loss and minor adverse events, which are discussed separately; ^b likely to require hospitalisation or further surgery

Minor complications occurred in up to 8.0 per cent of patients who received the X STOP (Table 17).

Table 17 Minor complications from the X STOP

Study	Level and quality	Population	Complications
(Lee et al 2004)	Level IV: Uncontrolled before-and-after case series Quality: 3/3	10 patients	No intra-operative complications or site-related post-operative complications such as implant failure, bony failure or infection
(Zucherman et al 2005)	Level IV: Single arm of randomised controlled trial Quality: 2.5/3	100 patients	8/100 (8.0%) patients: 1 case of respiratory distress (resolved without clinical sequelae) 1 coronary episode, ischaemic (resolved without clinical sequelae) 1 case of wound dehiscence 1 case of wound swelling 1 haematoma 1 case of incisional pain 1 asymptomatic spinous process fracture 1 case of increased pain at implant level

Secondary safety outcomes

Radiographic findings

Non-fusion devices are designed to move with the vertebrae, so loosening of the interspinous devices is expected and is not considered a complication. However, malpositioned implants are considered adverse events which may require intervention. One study assessed the safety of X STOP radiographically at 6-month follow-up, and found that two patients had radiologically detected complications or technical errors, although neither patient required further treatment (Zucherman et al 2005; Table 18).

Table 18 Radiographic observations after insertion of the X STOP

Study	Level and quality	Population	Radiographic observations
(Zucherman et al 2005)	Level IV: Single arm of randomised controlled trial Quality: 2.5/3	100 patients	2/100 (2%) patients: 1 asymptomatic spinous process fracture, requiring no further medical treatment or surgical intervention 1 malpositioned implant

Blood loss

One uncontrolled case series and one single arm of a randomised controlled trial (level IV evidence) reported low mean blood loss after insertion of the X STOP (Table 19).

Table 19 Blood loss from insertion of the X STOP

Study	Level and quality	Population	Mean blood loss (range)
(Lee et al 2004)	Level IV: Uncontrolled before-and-after case series Quality: 3/3	10 patients	≤100 mL
(Zucherman et al 2005)	Level IV: Single arm of randomised controlled trial Quality: 2.5/3	100 patients	46 mL

Safety of the Wallis system

Primary safety outcome

Minor adverse events

Only one study met the inclusion criteria outlined in Box 2 for the assessment of the Wallis device. This French prospective cohort study (level III-2 interventional evidence) compared the Wallis device (inserted after a discectomy) to a discectomy alone in a group of patients with recurrent herniated disc(s). No major adverse events were noted, and there was no significant difference in minor safety outcomes between the two treatment groups (Senegas 2002; Table 20).

Table 20 The safety of the Wallis device versus decompression

Study	Level and quality ^a	Population	Complications		Risk difference (95%CI)	Relative risk (95%CI)
			Wallis + decompression	Decompression		
(Senegas 2002)	Level III-2: Non-randomised controlled trial Quality: 18/27 Clin I: 4/4 R: 1/5	80 patients	7/40 (17.5%) patients: No infections 7 dural violations with no adverse consequences	6/40 (15%) patients: 2 superficial infections 4 intra-operative dural tears (1 of which turned into infectious meningitis that resolved without sequelae)	0.03 (-0.14, 0.19)	1.17 (0.43, 3.17)

^a See Appendix E— includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome).

Summary – Is lumbar non-fusion posterior stabilisation with/without decompression as safe as, or safer than, decompression or fusion surgery with/without decompression surgery?

Pedicle screw system

There were eight studies that assessed the safety of the Dynesys device. Serious complications occurred in a median of 5% of patients, which commonly included malpositioning of screws and pedicle fractures. The most common minor complications reported included dural lesions and superficial infections, occurring in up to 10% of patients. From limited comparative evidence the rate of complications after Dynesys insertion with decompression appears similar to decompression alone and to fusion with decompression. Radiography demonstrated screw breakage or loosening was evident in up to 16.7% of patients. No controlled studies had long enough follow-up to detect differences in the rate of screw breakage or loosening between the Dynesys and rigid instrumentation.

Interspinous non-fusion devices

Two studies met the inclusion criteria for determining the safety of the X STOP device. The rate of complications was low, although one death was reported in a patient who had previous cardiovascular disease and occurred as a consequence of pulmonary oedema. Blood loss from insertion of the X STOP procedure was minimal.

Only one study was identified that met the inclusion criteria for assessing the safety of the Wallis device. From this limited evidence, patients appeared to have a similar number of minor complications after receiving the Wallis device in addition to decompression than they did when they received decompression alone. No major complications were reported.

The Advisory Panel noted that the only evidence for safety for the Coflex and the DIAM devices was in abstract form (and excluded). However, since they have been widely used in Europe and the USA, the panel considered that this provided a measure of support for these devices.

Effectiveness of lumbar non-fusion posterior stabilisation

Studies assessing the effectiveness of lumbar non-fusion posterior stabilisation devices were included according to criteria outlined *a priori* in Box 3.

Box 3 Study selection criteria to determine the effectiveness of lumbar non-fusion posterior stabilisation

Research question	
Is lumbar non-fusion posterior stabilisation with/without decompression as effective as, or more effective than, decompression or fusion with/without decompression at providing post-operative leg pain relief and/or preventing post-operative back pain or worsening of back pain, and improving the quality of life or functional status of patients, with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise)?	
Selection criteria	Inclusion criteria
Population	People with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise) who have failed to respond to conservative management
Intervention	Lumbar non-fusion posterior stabilisation devices with/without decompression (eg X STOP, Wallis system, Dynesys, DIAM, Coflex)
Comparators	1) Decompression surgery (eg laminectomy, discectomy, nucleotomy) 2) Fusion surgery with/without decompression surgery (eg posterolateral gutter fusion, posterior lumbar interbody fusion, anterior lumbar interbody fusion, anterior/posterior spinal fusion)
Outcome	Primary—patient assessed leg and/or back pain, patient assessed quality of life, observer assessed functional status Secondary—observer assessed patient pain and quality of life, patient assessed functional status, analgesic usage, hospital length-of-stay ^b , rate of reoperation ^b , device removal ^b
Study design	Randomised or non-randomised controlled trials or cohort studies, uncontrolled before-and-after case series with at least 10 participants, or systematic reviews of these study designs
Search period	1994 – 2/2006 ^b
Language	Studies in languages other than English were only translated and included if they represented a higher level of evidence than that available in the English language evidence-base

^a For these outcomes post-test case series alone are also acceptable; ^b Research reports on the clinical use of lumbar non-fusion posterior stabilisation devices were first published in 1994.

A total of 11 studies contributed to the evidence base on the effectiveness of non-fusion devices for the lumbar spine; eight assessed the Dynesys, two assessed the X STOP and one assessed the Wallis device. Detailed profiles of the studies included in this assessment of effectiveness are provided in Appendix G. No studies assessing the DIAM or Coflex interspinous devices provided enough information to extract effectiveness outcome data.

Effectiveness of the Dynesys

The highest level of evidence assessing the effectiveness of the Dynesys came from two medium-quality historically controlled studies (level III-3 evidence) (Cakir et al 2003; Putzier et al 2005). The remaining evidence was from six uncontrolled before-and-after case series (level IV evidence).

Primary effectiveness outcomes

No studies in this review used observer-assessed functional status as an outcome measure. The two other primary outcomes defined *a priori* (patient-assessed pain and quality of life) are discussed below.

Patient-assessed pain

Pain before and after surgery was measured using a variety of instruments: visual analogue scale (VAS), Zurich claudication questionnaire (ZCQ) and the short form – 36 (SF-36; bodily pain subscale).

Visual analogue scale

Various forms of the VAS are used to measure subjective pain. The scales are valid and reliable and correlate well with other methods of measuring pain. A VAS is a straight line that represents the level of pain being experienced, either activity-specific or just at rest. Conventionally, the line is 10 cm long and each end of the scale is marked with labels indicating the range of pain, eg 0 = pain free, 10 = severe pain. Sometimes other line lengths are used (eg 5, 10, 15, 25 cm) and occasionally descriptors are placed along the line (eg severe, moderate, mild). The distribution of VAS scores is not normal and so non-parametric statistical analyses are appropriate (McDowell & Newell 1987). Initial and subsequent pain ratings on a VAS tend to be correlated, such that the magnitude of difference in scores before and after treatment is determined by the initial score. *Changes* in score should therefore be compared between groups, rather than simply the final post-treatment score.

Results of a historically controlled study assessing the effect of non-fusion stabilisation compared to decompression on pain using a VAS are presented in Table 21. When the Dynesys was compared against decompression surgery alone (nucleotomy), pain was similar between the groups at baseline. Reduction in pain from baseline was statistically significant at 3 months within both treatment groups; however, there was no statistically significant difference *between* the groups at this time point. At the subsequent follow-up (between 24 and 47 months), the mean VAS pain score for patients who had received nucleotomy was significantly increased ($p < 0.05$), whereas no increase in pain was noted in the patients who received Dynesys in addition to nucleotomy. Data were presented in graphical form, so exact measures cannot be reported.

Table 21 Effectiveness of the Dynesys at reducing pain (VAS; controlled studies)

Study	Level and quality ^a	Population	Change in pain ^b (VAS; 1-10 ^c)		Difference
			Decompression + Dynesys (n=35)	Decompression (n=49)	
(Putzier et al 2005)	Level III-3: Historical control study Quality: 19/27 Clin I: 3/4 R: 1/5	84 patients	p<0.05 ^d 74.3% with complete remission	p<0.05 ^d 71.4% with complete remission	Not significant ^d Not significant

^a See Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome); ^b change in pain compared to baseline; ^c VAS = visual analogue scale, where 0 = no pain, 10 = severe pain; ^d statistical tests were performed by 2-factorial analysis of variance with repetitive calculation for dependent and independent variables performed; results were verified by the Friedman test.

Additionally, two good-quality uncontrolled studies (level IV interventional evidence) reported on the impact of non-fusion posterior stabilisation of the lumbar spine on patient-assessed pain using a VAS (Table 22). Both articles that used a VAS to determine patient-assessed pain reported that the mean pain scores dropped considerably after insertion of the Dynesys. The minimum clinically significant difference on a VAS is reported to be between 9 mm and 13 mm on a 10-cm scale (Todd et al 1996; Kelly 2001). The lack of blinding of patients with regard to treatment may, however, have impacted on perception of pain due to expectation effects.

Table 22 Effectiveness of the Dynesys at reducing pain (VAS; uncontrolled studies)

Study	Level and quality	Population	Pain (VAS)		
			Pre	Post	Change ^a
(Stoll et al 2002b)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	73/83 patients	Back pain (VAS; 0–10) ^b		4.3 p<0.01 ^d
			7.4±2.6	3.1±2.3	
			Leg pain (VAS; 0–10) ^b		4.5 p<0.01 ^d
			6.9±3.0	2.4±2.1	
(Schnake et al 2006)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	24/26 patients	Mean pain (VAS; 0–100) ^c		57 p=0.00001
			80 range = 55–100	23 range = 0–82	

All statistical testing is compared to the pre-operative state; ^a change = absolute difference in the means; ^b VAS = visual analogue scale, where 0 = no pain, 10 = severe pain; ^c VAS = visual analogue scale, where 0 = no pain, 100 = severe pain; ^d Wilcoxon's matched-pair test

Short form – 36—bodily pain scale

The short form – 36 (SF–36) item questionnaire is a well-validated instrument, where each subscale ranges from 0 to 100 (0 = worst possible outcome and 100 = best possible outcome) (Pratt et al 2002). Two items on the SF–36 assess levels of bodily pain (Bowling 1997). A study on a United States population was done to determine normative data for the SF–36, and the mean score for bodily pain was 75.2±23.7 (Ware et al 1994). Currently, there is no standard reference for the minimal clinically significant improvement (Zanoli 2005).

One average-quality historically controlled study assessed pain using the SF–36 (Table 23). Three of 10 patients who underwent fusion complained of considerable post-operative pain associated with the site of the bone graft. Nevertheless, by 14 months follow-up the mean bodily pain subscale score had improved to a greater degree for patients receiving decompression and fusion surgery compared to patients who had decompression and implantation of the Dynesys device (Cakir et al 2003). Neither the statistical significance of the reduction in pain nor the difference between the groups was calculated (appropriately, given the small sample size). While the historically controlled study found substantial reduction in pain after surgery as a consequence of Dynesys implantation, mean SF–36 scores were still considerably lower than the normative data collated by Ware et al (1994).

Table 23 Effectiveness of the Dynesys at reducing pain (SF–36)

Study	Level and quality ^a	Population	Pain (SF–36; 0–100)						Relative change ^c
			Decompression + Dynesys (n = 10)			Decompression + fusion (n = 10)			
			Pre	Post	Change ^b	Pre	Post	Change ^b	
(Cakir et al 2003)	Level III-3: Historical control study Quality: 18/27 Clin I: 2/4 R: 1/5	20 patients	22	42	20	15	50	35	0.57

^a See Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome); ^b change = absolute difference in the means; ^c relative change = decompression + Dynesys change score / decompression + fusion change score; SF–36 = short form – 36, where 0 = worst possible outcome, 100 = best possible outcome.

Patient-assessed quality of life

Short form – 36—quality of life

The SF-36 is also commonly used to measure quality of life (McDowell & Newell 1996). It includes subscales of general health, mental health, role-emotional and vitality. Each subscale ranges from 0 = worst possible outcome to 100 = best possible outcome. A study was done to determine the normative scores within a North American population, and found that the mean scores were: for general health perceptions 72 ± 20.3 , mental health 74.7 ± 18.1 , role limitations (emotional problems) 81.3 ± 33.0 and vitality 72.0 ± 20.3 (Ware et al 1994).

One average-quality historically controlled study (level III-3 interventional evidence) assessed quality of life using the SF-36 (Table 24). While benefits were seen on most subscales for both treatment groups, Cakir et al (2003) did not assess the statistical significance of the change after intervention or the difference between the groups. Due to the small sample size of the study, no conclusions are able to be made on the comparative effectiveness of the Dynesys and decompression on improving quality of life compared to decompression with fusion.

Table 24 Effectiveness of the Dynesys at increasing quality of life (SF-36)

Study	Level and quality ^a	Population	Measure	Decompression + Dynesys (n = 10)			Decompression + fusion (n = 10)			Relative change ^c
				Pre	Post	Change ^b	Pre	Post	Change ^b	
(Cakir et al 2003)	Level III-3: Historical control study Quality: 18/27 Clin I: 4/4 R: 1/5	20 patients	General health	52	46	-6	31	45	14	-0.43
			Mental health	48	64	16	43	58	15	1.07
			Role emotional	7	56	49	15	37	22	2.23
			Vitality	32	42	10	25	45	20	0.50

^a See Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome); ^b change = absolute difference in means; ^c relative change = decompression + Dynesys change / decompression + fusion change; SF-36 = short form – 36, where 0 = worst possible outcome, 100 = best possible outcome.

Secondary effectiveness outcomes

No included studies used observer-assessed pain as an outcome; therefore, this outcome is not discussed. All other secondary measures of effectiveness selected a priori are discussed below.

Patient-assessed functional status

Functional status was assessed in the evidence base using the Oswestry disability index (ODI) and functioning subscales of the SF-36.

Oswestry disability index

The ODI is a validated questionnaire that was developed to measure impairment as a result of pain (McDowell & Newell 1987). The scale ranges from 0 to 50 but scores are converted to a percentage from the sections answered. A score of 0–20 represents

normal pain and function, 20–40 moderate disability, 40–60 severe disability, and over 60 severe disability from pain in several areas of life.

Two medium-quality historically controlled studies (level III-3 interventional evidence) assessed functioning using the ODI to compare the Dynesys against decompression with/without fusion surgery (Table 25). Cakir et al (2003) found that patients who received the Dynesys system and those who received fusion had mean ODI scores reduced from scores corresponding to severe disability to moderate disability. The difference between the groups was not statistically analysed. Although the patients who received decompression and the Dynesys device improved to a greater degree, this may be due to higher baseline levels of functional impairment and regression to the mean. Putzier et al (2005) found no significant difference in functioning between patients who received decompression with the Dynesys and decompression alone.

Table 25 Effectiveness of the Dynesys at improving functional status (ODI; controlled studies)

Study	Level and quality ^a	Population	Functional status (ODI; 0–100)						Relative Change ^c
			Pre	Post	Change ^b	Pre	Post	Change ^b	
(Putzier et al 2005)	Level III-3: Historical control study Quality: 19/27 Clin I: 3/4 R: 1/5	84 patients	Decompression + Dynesys (n = 35)			Decompression (n = 49)			No significant difference
			n/s	n/s	p<0.05	n/s	n/s	p<0.05	
(Cakir et al 2003)	Level III-3: Historical control study Quality: 18/27 Clin I: 2/4 R: 1/5	20 patients	Decompression + Dynesys (n = 10)			Decompression + fusion (n = 10)			1.5
			54	33	21	46	32	14	

ODI = Oswestry disability index, where 0 = no pain, 100 = severe pain; n/s = not stated; ^a see Appendix E, which includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome); ^b change = absolute difference in means; ^c relative change = intervention change / comparator change.

Two uncontrolled before-and-after case series (level IV interventional evidence) also used the ODI to determine functional status before and after insertion of the Dynesys (Table 26). While both studies found an improvement at follow-up, only one of the studies assessed the statistical significance of the observed benefit and concluded the effect was likely to be real (above chance).

Table 26 Effectiveness of the Dynesys at improving functional status (ODI; uncontrolled studies)

Study	Level and quality	Population	Mean disability (ODI; 0–100)		
			Pre	Post	Change ^a
(Stoll et al 2002b)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	73/83 patients	55.4±19.5 range = 10–92	22.9±19.3 range = 0–71	32.5 p<0.01 ^b
(Bordes-Monmeneu et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 2/3	95 patients	56.8	21.4	35.4 ^c

ODI = Oswestry disability index, where 0 = no pain, 100 = severe pain; ^a change = absolute difference in means; ^b Wilcoxon's matched-pair test; ^c significance level not stated

Short form – 36—functioning subscales

The SF-36 includes subscales of physical functioning, role limitations due to physical problems and social functioning (Bowling 1997). One average quality historically controlled study (level III-3 interventional evidence) (Table 27) assessed functioning using the SF-36. Decompression plus Dynesys was compared against decompression plus fusion but no statistical comparisons were made. Both treatments improved patient functioning as measured on these subscales of the SF-36 by between 14 and 25 points.

Table 27 Effectiveness of the Dynesys at improving functional status (SF-36)

Study	Level and quality ^a	Population	Measure	Functioning (SF-36; 0–100)						Relative change ^c
				Decompression + Dynesys (n = 10)			Decompression + fusion (n = 10)			
				Pre	Post	Change ^b	Pre	Post	Change ^b	
(Cakir et al 2003)	Level III-3: Historical control study Quality: 18/27 Clin I: 2/4 R: 1/5	20 patients	Physical function	23	42	19	18	39	21	0.90
			Social function	44	58	14	43	60	17	0.83
			Role physical	14	39	25	14	31	17	1.47

^a See Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome); SF-36 = short form – 36 where 0 = worst possible outcome, 100 = best possible outcome; ^b change = absolute difference in means; ^c relative change = decompression + Dynesys change / decompression + fusion change

Analgesic usage

Analgesic use is a surrogate measure of pain, and therefore can be used to determine the effectiveness of non-fusion stabilisation. Only one study reported rates of analgesic use before and after non-fusion stabilisation (Table 28). The 26 patients with lumbar spinal stenosis and degenerative spondylolisthesis who underwent stabilisation with Dynesys used statistically significantly less analgesics 2 years after stabilisation than before.

Table 28 Effectiveness of the Dynesys at reducing analgesic use

Study	Level and quality	Population	Analgesic use		
			Pre (n = 26)	Post (n = 24)	Change ^a
(Schnake et al 2006)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	26 patients	19	6	13 p=0.013

LSS = lumbar spinal stenosis; ^a change = absolute difference in means

Hospital length of stay

One average quality historically controlled study (level III-3 interventional evidence) compared the effects of decompression surgery with dynamic stabilisation against decompression surgery with dorsoventral fusion in a group of patients with degenerative spinal stenosis (Cakir et al 2003). This German study found that the average length of hospital stay was considerably less after insertion of the Dynesys device than after fusion surgery (Table 29). It is likely that hospital length of stay associated with the insertion of a lumbar non-fusion device is dependent on the type of anaesthesia given to the patient, the co-morbidities of the patient and the local hospital protocols regarding patient discharge and outpatient follow-up. Hospital length of stay results from Cakir et al (2003)

are not representative of the Australian situation. In 2003–04, the average length of hospital stay (private and public combined) after spinal fusion was 9.1 days (Australian Government Department of Health and Ageing 2005).

Table 29 Effectiveness of non-fusion stabilisation at reducing length of hospital stay (controlled study)

Study	Level and quality ^a	Population	Mean length of stay (range)	
			Decompression + Dynesys (n = 10)	Decompression + fusion (n = 10)
(Cakir et al 2003)	Level III-3: Historical control study Quality: 18/27 Clin I: 2/4 R: 3/5	20 patients	19.3 days (11–28 days)	28.4 days (16–37 days)

^a See Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome).

Two uncontrolled case series (level IV interventional evidence) reported hospital length of stay after insertion of the Dynesys device ranging between 9 and 43 days (Table 30).

Table 30 Length of hospital stay after insertion of the Dynesys (uncontrolled studies)

Study	Level and quality	Population	Mean hospital length of stay (range)
(Schnake et al 2006)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	26 patients	16 days (10–43 days)
(Putzier et al 2004)	Level IV: Uncontrolled before-and-after case series Quality: 1/3	70 patients	13 days (9–19 days)

Reoperation

Further treatment at the site of a non-fusion implant due to persisting problems was classified as a therapeutic failure. Five uncontrolled case series provided information on reoperation rates (Table 31). Between 3.8 and 12.9 per cent of patients who received the Dynesys required reoperation at the index level.

Table 31 Reoperation rates after insertion of the Dynesys

Study	Level and quality	Population	Reoperation
(Dubois et al 1999)	Level IV: Uncontrolled before-and-after case series Quality: 3/3	57 patients	4/57 (7.0%) patients: 2 cases where device was placed extrapedicularly, causing neurologic symptoms 2 cases where investigator decided to perform arthrodesis
(Stoll et al 2002b)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	73/83 patients	6/73 (8.2%) patients: <i>Screw loosening</i> 1 screw malpositioned, which required reoperation 1 screw loosening causing clinical symptoms which required further intervention <i>Index level</i> 3 cases of implant removal due to unresolved pain – revision to fusion in 2 1 patient required laminectomy at index level <i>Adjacent level degeneration</i> 7 (9.5%) patients with adjacent segment degeneration required further surgery: 1 underwent decompression of adjacent segment, removal of implant and extended fusions 4 underwent implant removal and extended fusions 2 received extension of Dynesys
(Schnake et al 2006)	Level IV: Uncontrolled before-and-after case series Quality: 2.5/3	26 patients	1/26 (3.8%) patients: 1 required revision secondary to insufficient decompression
(Grob et al 2005)	Level IV: Uncontrolled before-and-after case series Quality: 1.5/3	31 patients	4/31 (12.9%) patients: 4 cases of implant loosening (revised to fusion) 2 further cases showed signs of screw loosening with a view to possible revisions
(Putzier et al 2004)	Level IV: Uncontrolled before-and-after case series Quality: 1/3	70 patients	5/70 (7.1%) patients: 2 cases of screw loosening treated with complete implant removal 1 screw breakage treated with dorsoventral spondylodesis 1 newly developed radicular syndrome treated with radiculolysis 1 progressive motor radicular syndrome treated with dorsoventral spondylodesis

Effectiveness of interspinous non-fusion devices

Effectiveness of the X STOP

Two studies met the inclusion criteria determined a priori (see assessing the effectiveness of the X STOP (Box 3).

Primary effectiveness outcomes

No studies in this review used observer-assessed functional status as an outcome measure. The two other primary outcomes defined a priori (patient-assessed pain and quality of life) are discussed below.

Patient-assessed pain

Pain before and after insertion of the X STOP was measured using the short form– 36 (SF–36; bodily pain subscale) and the Zurich claudication questionnaire (ZCQ).

Short form – 36 (SF–36)—bodily pain scale

Zucherman et al (2004) performed a randomised controlled trial comparing the X STOP interspinous implant with non-operative therapy. While the comparator was inappropriate for the purposes of this systematic review, the data from the patients who received the X STOP device were included. This good-quality multicentre study (level IV interventional evidence) found that mean pain was significantly lower 1 year post-insertion of the X STOP device than prior to surgery (Table 32).

Table 32 Effectiveness of the X STOP at reducing pain

Study	Level and quality	Population	Pain (SF–36;0–100)		
			Pre	Post	Change ^a
(Zucherman et al 2004)	Level IV: Single arm of randomised controlled trial Quality: 2.5/3	88/100 patients	24.5	56.1	31.6 p<0.05 ^b

^a change = absolute difference in means; ^b student's t-test; SF–36 = short form – 36, where 0 = worst possible outcome, 100 = best possible outcome.

Zurich claudication questionnaire

The Zurich claudication questionnaire (ZCQ), also known as the Swiss spinal stenosis questionnaire (SSS), is a validated instrument specific to lumbar spinal stenosis (Zucherman et al 2004). It has three different domains (symptom severity, physical function and post-treatment satisfaction). Questions 1 to 7 assess symptoms severity, including pain, and a neuroischaemic domain (Pratt et al 2002). Each question receives a score out of 5 and the scores are averaged for each domain. Two uncontrolled studies (level IV interventional evidence) used the ZCQ and found reductions of symptom severity in patients who had received the X STOP device (Table 33). A clinically important reduction in symptom severity on the ZCQ is defined as post-operative average score – pre-operative average score ≥ 0.5 . Between 40 and 60 per cent of patients had a clinically important reduction in symptoms after insertion of the X STOP device (9 months – 2 years after surgery).

Table 33 Effectiveness of the X STOP at reducing pain (ZCQ)

Study	Level and quality	Population	Pain (ZCQ; 1–5)		
			Pre	Post	Change
(Lee et al 2004)	Level IV: Uncontrolled before-and-after case series Quality: 3/3	10 patients	2.74	9–18 months 2.26	0.49 significant improvement in 40% ^a
(Zucherman et al 2004) (Zucherman et al 2005)	Level IV: Single arm of randomised controlled trial Quality: 2.5/3	93/100 patients	3.14 (1.60–3.60)	2 years Not stated	45.5% p<0.05 ^b significant improvement in 60.2% ^a

^a significant improvement = post-operative score – pre-operative score ≥ 0.5 ; ^b student's t-test

Patient-assessed quality of life

Quality of life—SF-36

One good-quality arm of a randomised controlled trial (level IV interventional evidence) assessed quality of life using the SF-36 (Table 34). Zucherman et al (2004) had a large enough sample size that the mean changes after 1 year on all subscales were statistically significant despite the small changes for general health perception and mental health. The clinical importance of these differences is unclear.

Table 34 Effectiveness of the X STOP at increasing quality of life (SF-36)

Study	Level and quality	Population	Quality of life (SF-36)			
			Measure	Pre	Post	Change ^a
(Zucherman et al 2004)	Level IV: Single arm of randomised controlled trial Quality: 2.5/3	88/100 patients	General health	70.2	73.0	2.8, p<0.05 ^b
			Mental health	64.6	66.8	2.2, p<0.05 ^b
			Role emotional	52.0	77.1	25.1, p<0.05 ^b
			Vitality	47.4	53.0	5.6, p<0.05 ^b

^a change = absolute difference in means; SF-36 = short form – 36, where 0 = worst possible outcome, 100 = best possible outcome; ^b student's t-test;

Secondary effectiveness outcomes

No included studies used observer-assessed pain as an outcome; therefore, this outcome is not discussed. All other secondary measures of effectiveness selected a priori are discussed below.

Patient-assessed functional status

Functional status was assessed in the evidence base using the functioning subscales of the short form – 36 (SF-36) and the Zurich Claudication Questionnaire (ZCQ).

Short form – 36—functioning subscales

One good-quality single arm of a randomised controlled trial (level IV evidence) (Table 35) assessed functioning using the SF-36. The single arm study found greater benefits of between 20.8 and 43.5 points for the functioning subscales of the SF-36, all of which were statistically significant at 1 year follow-up.

Table 35 Effectiveness of the X STOP at improving functional status (SF-36)

Study	Level and quality	Population	Functioning (SF-36; 0-100)			
			Measure	Pre	Post	Change ^a
(Zucherman et al 2004)	Level IV: Single arm of randomised controlled trial Quality: 2.5/3	88/100 patients	Physical function	31.7	62.2	30.5, p<0.05 ^b
			Social function	58.5	79.3	20.8, p<0.05 ^b
			Role physical	13.5	57.0	43.5, p<0.05 ^b

SF-36 = short form – 36 where 0 = worst possible outcome, 100 = best possible outcome; ^a change = absolute difference in means; ^b student's t-test

Zurich claudication questionnaire

Two good-quality studies (level IV evidence) used the ZCQ to assess physical functioning before and after insertion of the X STOP device (Table 36). A clinically important improvement on the ZCQ physical function subscale is defined as a ≥ 0.5 reduction in score. Clinically significant improvements were seen in 10–57 per cent of patients. The difference in rate of clinical success may be attributable to learning curves of the surgeon, as the larger case series reported much better success at improving patient-assessed functioning than the smaller case series.

Table 36 Effectiveness of the X STOP at improving functional status (ZCQ)

Study	Level and quality	Population	Functional status (ZCQ; 1-4)		
			Pre	Post	Change ^a
(Lee et al 2004)	Level IV: Uncontrolled before-and-after case series Quality: 3/3	10 patients	2.33	9–18 months 2.12	0.21 significant improvement in 10%
(Zucherman et al 2004) (Zucherman et al 2005)	Level IV: Single arm of randomised controlled trial Quality: 2.5/3	93/100 patients	2.48 (1.60–3.60)	2 years Not stated	44.3% reduction in mean ZCQ score p<0.05 ^b significant improvement in 57%

ZCQ = Zurich claudication questionnaire, where 1 = no pain, 4 = severe pain; significant improvement = reduction of 0.5 or more on ZCQ; ^a change = absolute difference in means; ^b student's t test

Reoperation

Reoperation at the index level is considered a therapeutic failure. Zucherman et al (2005) reported that six patients (6.5% of those followed up) who received the X STOP device underwent decompression surgery (laminectomy) due to unresolved stenosis symptoms during a 2 year follow-up period (Zucherman et al 2005).

Effectiveness of the Wallis device

One average quality French non-randomised study (level III-2 evidence) was identified that reported on the effectiveness of the Wallis device and met the inclusion criteria determined a priori (Box 3). Patients were undergoing surgery for recurrence of herniated disc, and received a discectomy with or without the Wallis device at L4–L5. This study assessed patient pain (VAS), functioning (ODI), analgesic use and reoperation rates. While the patients in this study received the first generation of the Wallis device (made from titanium), the Advisory Panel decided that the first generation device was sufficiently similar to the current device (made from polyetheretherketone; PEEK) that the results would be comparable.

Primary effectiveness outcomes

Patient-assessed functional pain

Visual analogue scale

A description of the VAS can be found on page 35. Change in pain scores at follow-up (average 3 years and 4 months) were higher in the group who received the Wallis implant after their discectomy than in those who received a discectomy alone, showing a larger reduction in pain (Table 37). Raw outcome data were not presented in the research article, and no statistical comparison was made between the two treatment groups. Losses to follow-up were not reported, which could potentially be a confounding factor.

Table 37 Effectiveness of the Wallis at reducing pain (VAS)

Study	Level and quality ^a	Population	Change in pain ^b (VAS; 1–10 ^c)		Difference
			Decompression + Wallis (n = 40)	Decompression (n = 40)	
(Senegas 2002)	Level III-2: Non-randomised controlled trial Quality: 18/27 Clin I: 1/4 R: 1/5	80 patients	74%	52%	Not stated

^a See Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome); ^b change in pain compared to baseline; ^c VAS = visual analogue scale, where 0 = no pain, 10 = severe pain

Secondary effectiveness outcomes

Patient-assessed functional status

Oswestry disability index

Senegas (2002) used the Oswestry disability index (ODI) to assess the functional status of patients prior to and after surgery (for a full description of the ODI questionnaire see page 37). Greater improvement in patient-assessed functional status was reported at follow-up (average 3 years 4 months, minimum of 1 year) after decompression plus the Wallis device than after decompression alone (Table 38). However, the loss to follow-up was not reported, so results may be affected by attrition bias.

Table 38 Effectiveness of the Wallis at improving functional status (ODI)

Study	Level and quality ^a	Population	Functional status (ODI; 0–100)						Relative Change ^c
			Pre	Post	Change ^b	Pre	Post	Change ^b	
(Senegas 2002)	Level III-2: Non-randomised controlled trial Quality: 18/27 Clin I: 1/4 R: 1/5	80 patients	Decompression + Wallis (n = 40)			Decompression (n = 40)			1.28
			58.2±22	16.4±10	41.8	54.7±16	22±11	32.7	

ODI = Oswestry disability index, where 0 = no pain, 100 = severe pain; ^a see Appendix E—includes the level of evidence, a quality score derived from the Downs and Black (1998) checklist (with a high score indicating good quality), rank scores for assessing the clinical importance (Clin I) of the benefit/harm (with 1 ranked as highly clinically important and 4 ranked as of indeterminate clinical importance) and rank scores for the relevance (R) of the evidence (with 1 ranked as a highly relevant outcome and 5 as an unproven surrogate outcome); ^b change = absolute difference in means; ^c relative change = intervention change / comparator change.

Analgesic usage

Analgesic use is a surrogate measure of pain, and therefore can be used to determine the effectiveness of non-fusion stabilisation. The rate of analgesic usage prior to surgery is unknown; however, substantially fewer patients who received the Wallis device were taking analgesics after surgery than those in the discectomy-alone group (Table 39).

Table 39 Effectiveness of the Wallis at reducing analgesic use

Study	Level and quality	Population	Analgesic usage post surgery	
(Senegas 2002)	Level III-2: Non-randomised controlled trial Quality: 18/27	80 patients	Decompression + Wallis (n = 40)	Decompression (n = 40)
			42.5% no longer taking analgesics	20% no longer taking analgesics

Reoperation

Further treatment at the site of a non-fusion implant due to persisting problems was classified a therapeutic failure. Senegas (2002) reported no difference in rate of reoperations between the patients who received discectomy and the Wallis device versus a discectomy alone (Table 40).

Table 40 Effectiveness of the Wallis at reducing rate of reoperation

Study	Level and quality	Population	Reoperations		Risk difference (95%CI)	Relative risk (95%CI)
(Senegas 2002)	Level III-2: Non-randomised controlled trial Quality: 18/27	80 patients	Decompression + Wallis (n = 40)	Decompression (n = 40)	0.00 (−0.12, 0.12)	1.00 (0.22, 4.66)
			3/40 (7.5%) patients: 3 cases of persisting low-back pain (1 case where ligament was loose; 2 cases of subsequent disc herniation)	3/40 (7.5%) patients: 2 reoperations due to chronic low-back pain (revised to fusion) 1 neurostimulation device implanted due to constant pain		

Summary – Is lumbar non-fusion posterior stabilisation with/without decompression as effective as, or more effective than, decompression or fusion with/without decompression at providing post-operative leg pain relief and/or preventing post-operative back pain or worsening of back pain, and improving the quality of life or functional status of patients with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise)?

Pedicle screw system

Two average-quality historically controlled studies (level III-3 evidence) and six uncontrolled before-and-after case series (level IV evidence) provided information on the effectiveness of the Dynesys device. The Dynesys was found to be as effective at reducing pain as decompression alone and less effective than fusion surgery (both performed after decompression surgery), although the sample size of the study was too small (n=20) to determine the significance of this finding. Two uncontrolled studies further reported that the Dynesys was effective at reducing pain from baseline.

One historically controlled study found that decompression + Dynesys and decompression + fusion improved the mean scores on the subscales of mental health, role emotional and vitality, whereas only patients receiving decompression + fusion surgery improved on the general health perceptions subscale. Patients who received decompression + Dynesys had a reduction (worsening) of mean general health perceptions score. Patient-assessed functional status was improved after insertion of the Dynesys. The two comparative studies found that the Dynesys was as effective as decompression with/without fusion surgery at improving functional status.

Hospital length of stay was found to be significantly shorter after decompression + insertion of the Dynesys (19.3 days) than decompression + fusion of the vertebral bodies (28.4 days) (level III-3 evidence). These results are unlikely to be relevant to Australia given the quite different hospital discharge practices. However, interspinous devices are likely to result in shorter lengths of stay than the Dynesys.

Interspinous non-fusion devices

Two studies without appropriate control conditions provided before-and-after effectiveness data on the X STOP (level IV evidence). One good-quality single arm of a randomised controlled trial found statistically significant improvements for patients after the insertion of the X STOP device on all subscales of the SF-36 (including pain, functioning and quality of life), although the clinical importance of these changes is unclear. Significant reductions in pain on the Zurich claudication questionnaire were found in 40–60% of patients, and significant improvements in functional status were found in 10–57% of patients.

One average quality cohort study (level III-2 evidence) assessed the effectiveness of the Wallis device following a discectomy, compared to a discectomy alone. Patients who received the Wallis device had a greater reduction in pain and larger improvement in functioning than those who received the discectomy alone, although the statistical and clinical significance of these differences is unclear. Substantially fewer patients required analgesics after receiving the Wallis device, while no significant difference was found between the rates of reoperation between patient groups.

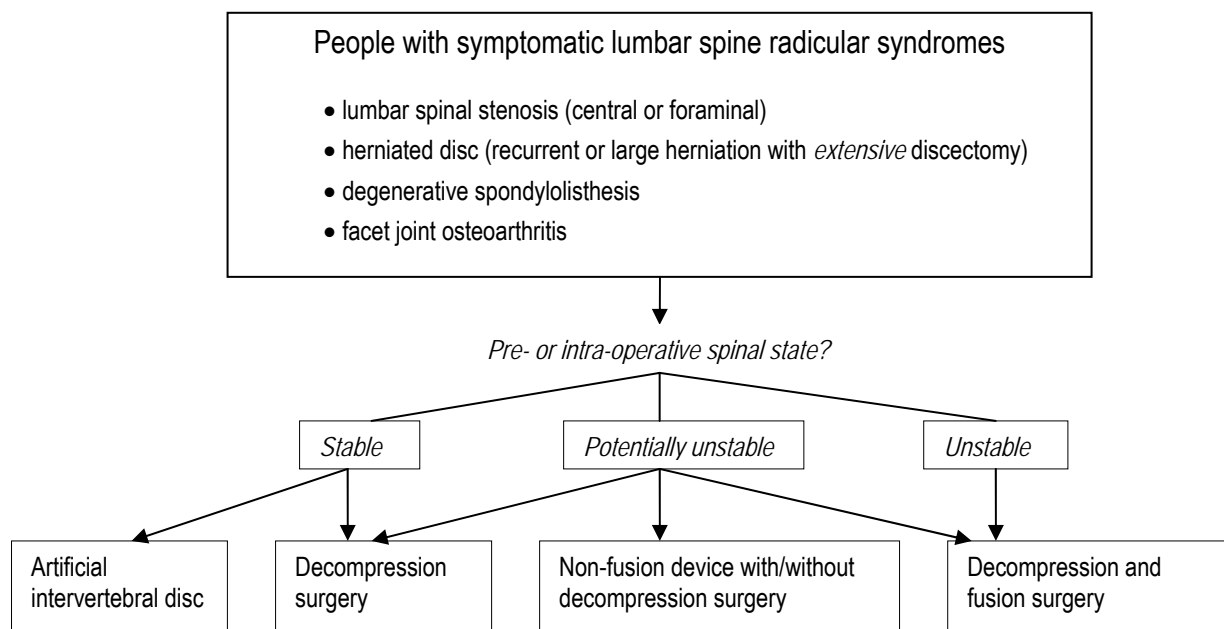
Economic considerations for lumbar non-fusion posterior stabilisation

The purpose of the economic evaluation is to consider the additional costs and additional health gains of the proposed service over the comparator when used in the Australian healthcare system. Despite non-inferiority not having been formally tested, the Advisory Panel concluded that, on the balance of the evidence presented, lumbar non-fusion posterior stabilisation devices are as safe as and no less effective than the main comparators, decompression surgery or fusion surgery with/without decompression. A cost analysis is therefore presented.

The present economic evaluation will focus on the costs and health outcomes from a societal perspective. This includes costs to the Australian Government (MBS), the States and Territories, and the individual and/or their health insurance company. Cost data will therefore cover all non-trivial resources directly used in providing the intervention. Indirect costs, also known as productivity costs, are not considered. All cost data were converted to the single year 2006 and expressed in Australian dollars.

Research question: Is lumbar non-fusion posterior stabilisation with decompression a less costly treatment option for patients with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise) in comparison to decompression alone or fusion with decompression?

Figure 8 Clinical decision tree for symptomatic lumbar radicular compromise refractory to conservative treatment



The main comparators used in these analyses are decompression surgery alone and decompression plus fusion surgery. Fusion surgery is occasionally performed without prior decompression, and was therefore included in the systematic review as a comparative treatment; however, for the purposes of the economic evaluation, it will not

be considered as it is not common clinical practice for fusion surgery alone to be performed for this patient group in Australia.

Non-fusion stabilisation devices are expected to replace a proportion of fusion procedures (both performed after decompression surgery) as well as a proportion of decompression procedures.

Thus, the main comparisons considered in this economic analysis are:

- decompression and stabilisation with a non-fusion device versus decompression
- decompression and stabilisation with a non-fusion device versus decompression and fusion

Five non-fusion devices are relevant to each main comparison.

It is accepted that the two comparators are not discretely independent. In theory, there are defined patient characteristics; however, in reality, patients will present with subtle gradations of symptoms and signs that represent a continuum of characteristics. The surgeon determines the most appropriate surgery to be performed for that individual (decompression alone or with the addition of fusion) based on their knowledge and experience that the merits of one is greater than that of the other. In view of this, the Advisory Panel therefore recommended that it was appropriate to compare conventional surgery (decompression with or without fusion) with decompression and non-fusion surgery.

Cost analysis

Patient population

The population for whom Medicare Benefits coverage is being considered are those patients with lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with symptomatic radicular compromise) that has failed to respond to conservative management.

The population included in the economic analysis are those who currently receive the comparator treatments (ie laminectomy or laminectomy and posterior fusion surgery). The actual target population would include a small number of patients who have herniated discs and require a discectomy; however, for the purposes of the economic evaluation, the potential uptake of non-fusion devices has been based on the number of laminectomy procedures undertaken. Including the number of discectomies would result in a gross overestimation of potential use.

The population included in the economic analysis does not include those patients who currently would not be considered for surgery. It is possible that a small number of people with mild lumbar spinal stenosis who would not be considered for decompression surgery or fusion surgery may receive the X STOP device. For the Australian healthcare context and from the societal perspective, the target population is therefore all patients who would be considered for the comparator treatments (and could thus be considered for non-fusion devices) in both the public and private healthcare systems.

The evidence of effectiveness and safety presented in this report is for patients who received non-fusion devices in different healthcare settings around the world. The

Advisory Panel has accepted that these results would be generalisable to the Australian population (with the exception of hospital length of stay data) since the evidence comes from developed countries¹ with similar standards of practice to Australia.

Resources considered during the economic evaluation

Table 41 lists the main types of resources considered in the economic analysis and the source of the information for their unit costs.

Table 41 Main types of resources considered in the economic analysis and the source of the information on unit costs

Type of cost	Source of information
Medical practitioner services	2005 Schedule of Medicare Benefits, Department of Health and Ageing, Australian Government, < http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Medicare+Benefits+Schedule-2 >
Prostheses	2005 Prostheses list (plus 2006 amendments), Australian Health Insurance Association, < http://www.ahia.org.au/prostheses.php >; Zimmer Spine and Taylor Bryant
Hospital and theatre accommodation	2003-4 Round 7 Cost Report AR-DRG for private hospitals, Department of Health and Ageing, Australian Government, < http://www.health.gov.au/internet/wcms/publishing.nsf/Content/Data+Collections-1 >

Medical practitioner services

The unit costs of medical practitioner services were obtained from the likely MBS fees for surgery involving lumbar non-fusion posterior stabilisation devices compared to the MBS fees currently listed for decompression and fusion surgery.

Table 42 outlines the number of vertebral levels treated within the non-fusion literature. These rates are similar to the number of levels of rigid instrumentation, as determined from the ratio of item number usage on the MBS (Medicare Australia 2006). A small number of patients (3.6%) receive more than four levels of fusion instrumentation (Medicare Australia 2006) but it is unlikely that these patients would be candidates for non-fusion devices.

Table 42 Estimated number of vertebral levels requiring treatment (in patients suitable for non-fusion devices)

Number of vertebral levels	Percentage of patients
1	65
2	20
3	10
4	5
More than 4	0

The cost associated with the non-fusion and comparative procedures varies substantially depending on the number of levels treated, the type of device/instrumentation used, and the type of decompression surgery used. The complexity of the surgery also influences how much anaesthesia would be used. Therefore, weighted estimates of the unit cost

¹ United Kingdom, Spain, Germany, Australia, United States, France, Switzerland, Italy, Korea, Japan and Sweden

have been derived by determining the percentage of the patient population likely to be over 70 years of age, the percentage likely to have more than one level of instrumentation, and the assumption that patients will receive the more common form of decompression (items 40303 and 40306).

Assumptions that have been made are:

- The pre-procedural work-up is the same between treatments and has therefore not been included in the total cost of the procedures.
- Sixty-five per cent of patients are treated at one vertebral level, 20 per cent at two levels, 10 per cent at three levels and 5 per cent at four levels (based on a combination of the usage of MBS items 48684 and 48687 and the number of levels treated in the non-fusion literature).
- 27 per cent of the patients are aged 70 years or greater (based on the age distribution of claims against MBS item numbers 40300, 40301, 40303 and 40306 in 2005–06). This is important for estimating the percentage of patients for whom an age modifier is required (for the costing of anaesthesia).
- All patients undergo rhizolysis as part of the decompression surgery.

Decompression surgery

Table 43 describes all MBS item numbers likely to be relevant to a common form of decompression surgery (laminectomy for one or more vertebral levels for recurrent disc lesion or spinal stenosis) and Table 44 shows the weighted average cost of the surgery.

Table 43 MBS items associated with laminectomy

Resource item	Cost	Percentage of patients	Source of data
Anaesthesia			
Anaesthesia initiation	\$137.20	100%	MBS item 20630
Time units 46–50 minutes ^a	\$68.60	65%	MBS item 23041 Time units sourced from Putzier et al 2005 Estimated % of patients based on number of levels treated in the evidence base
OR			
Time units 1:26–1:30 hours ^b	\$102.90	35%	MBS item 23063 Time units sourced from Advisory Panel Estimated % of patients based on number of levels treated in the evidence base
Age modifier (over 70 years)	\$17.15	27%	MBS item 25015 % of patients based on age distribution of patients undergoing decompression—MBS 2005–06 statistics
Decompression surgery			
Laminectomy for 1 level recurrent disc lesion or spinal stenosis	\$943.65	65%	MBS item 40303 Estimated % of patients based on number of levels treated in the evidence base
OR			
Laminectomy for more than 1 level of spinal stenosis	\$1,243.05	35%	MBS item 40306 Estimated % of patients based on number of levels treated in the evidence base
Spinal rhizolysis to expose nerve roots	\$826.50	100%	MBS item 40330 (50% of second most expensive procedure) % of patients assumed for simplicity of analyses
Assistance at operation	20% of surgery costs	100%	MBS item 51303
Intra-operative imaging			
Fluoroscopy for less than 1 hour	\$63.75	65%	MBS item 60506 Estimated % of patients based on number of levels treated in the evidence base
OR			
Fluoroscopy for more than 1 hour	\$98.90	35%	MBS item 60509 Estimated % of patients based on number of levels treated in the evidence base

MBS item costs from Medicare Australia; ^a estimated time of surgery on one vertebral level; ^b estimated time of surgery for two or more vertebral levels

Table 44 Calculations for weighted average cost of decompression surgery

	1 level		2 or more levels	
	MBS item	Cost	MBS item	Cost
Anaesthesia				
100%	20630	\$137	20630	\$137
100%	23041	\$69	23063	\$103
27%	25015	\$5	25015	\$5
total		\$211		\$245
Surgery ^a				
100%	40303	\$944	40306	\$1,243
50%	40330	\$413	40330	\$413
total		\$1,357		\$1,656
Assistant				
20% of surgery	51303	\$271	51303	\$331
Imaging	60506	\$64	60509	\$99
Total		\$1,903		\$2,331
Weighting ^b	0.65		0.35	
Weighted average		\$2,053		

^a When two or more operations are performed on the patient on one occasion, the schedule fee is as follows: 100% of most expensive item, 50% of next most expensive item, 25% of remaining items (Health Insurance Commission 2003); ^b weighting based on number of vertebral levels treated (Table 42)

Decompression and fusion surgery

The estimated unit cost of fusion surgery to the MBS has been approximated based on the two common combinations of fusion surgery. Table 45 outlines the MBS item numbers that are likely to be claimed during a hospital stay for decompression and fusion surgery and Table 46 shows the weighted average cost of the surgery.

Table 45 MBS items associated with decompression and fusion surgery

Resource item	Cost	Percentage of patients	Source of data
Anaesthesia			
Anaesthesia initiation	\$222.95	100%	MBS item 20670
Time units 2:51–3:00 hours ^a	\$240.10	65%	MBS item 23114 Estimated % of patients based on number of levels treated in the evidence base
OR			
Time units 4:21–4:30 hours ^b	\$394.45	35%	MBS item 23190 Estimated % of patients based on number of levels treated in the evidence base
Age modifier (over 70 years)	\$17.15	27%	MBS item 25015 % of patients based on age distribution of patients undergoing decompression—MBS 2005–06 statistics
Decompression surgery			
Laminectomy for 1 level of recurrent disc lesion or spinal stenosis	\$943.65	65%	MBS item 40303 Estimated % of patients based on number of levels treated in the evidence base
OR			
Laminectomy for more than 1 level of spinal stenosis	\$1,243.05	35%	MBS item 40306 Estimated % of patients based on number of levels treated in the evidence base
Spinal rhizolysis to expose nerve roots	\$826.50	100%	MBS item 40330 % of patients assumed for simplicity of analyses
Fusion surgery			
Bone graft harvesting	\$203.75	100%	MBS item 47729 % of patients assumed for simplicity of analyses
Bone graft (posterolateral fusion) 1 or 2 levels	\$937.00	85%	MBS item 48648 Estimated % of patients based on number of levels treated in the evidence base
OR			
Bone graft (posterolateral fusion) 3 or 4 levels	\$1,303.70	15%	MBS item 48651 Estimated % of patients based on number of levels treated in the evidence base
Internal fixation 1 or 2 levels	\$814.85	85%	MBS item 48684 Estimated % of patients based on number of levels treated in the evidence base
OR			
Internal fixation 3 or 4 levels	\$1,140.60	15%	MBS item 48687 Estimated % of patients based on number of levels treated in the evidence base
Assistance			
Assistance at operation	20% of surgery costs	100%	MBS item 51303
Intra-operative imaging			
Fluoroscopy for more than 1 hour	\$98.90	100%	MBS item 60509 Estimated % of patients based on number of levels treated in the evidence base

MBS item costs from Medicare Australia; ^a estimated time of surgery on one vertebral level; ^b estimated time of surgery for two or more vertebral levels; BMP = bone morphogenetic proteins

Table 46 Calculations for weighted average cost of decompression and fusion surgery

	1 level		2 levels		3 or 4 levels	
	MBS item	Cost	MBS item	Cost	MBS item	Cost
Anaesthesia						
100%	20670	\$223	20670	\$223	20670	\$223
100%	23114	\$240	23190	\$394	23190	\$394
27%	25015	\$5	25015	\$5	25015	\$5
total		\$468		\$622		\$622
Surgery^a						
100%	40303	\$944	40306	\$1,243	48651	\$1,304
50%	48648	\$469	48648	\$469	40306	\$622
25%	40330	\$207	40330	\$207	40330	\$207
25%	48684	\$204	48684	\$204	48687	\$570
25%	47729	\$51	47729	\$51	47729	\$51
total		\$1,873		\$2,173		\$2,753
Assistant						
20% of surgery	51303	\$375	51303	\$410	51303	\$551
Imaging	60509	\$99	60509	\$99	60509	\$99
Total		\$2,815		\$3,328		\$4,025
Weighting^b	0.65		0.20		0.15	
Weighted average	\$3,099					

^a When two or more operations are performed on the patient on one occasion, the schedule fee is as follows: 100% of most expensive item, 50% of next most expensive item, 25% of remaining items (Health Insurance Commission 2003); ^b weighting based on number of vertebral levels treated (Table 42)

Non-fusion devices

Assumptions that have been made in determining the cost of inserting a non-fusion device are:

- The number of levels treated would be the same for the comparator treatment of fusion surgery (ie 65% at one level, 20% at two levels, 10% at three levels, 5% at four levels).
- The best estimate of the unit cost of inserting a non-fusion *interspinous* device is the MBS item 48678 (Table 47) (SPINE, simple internal fixation of, involving 1 or more facet screw, wire loop or similar, being a service associated with a service to which items 48642 to 48675 apply (Anaes.) (Assist.)).
- The best estimate of the unit cost of inserting a non-fusion *pedicle screw* device (Dynesys) is the weighted average of the MBS items 48684 and 48687 (Table 48) (SPINE, segmental internal fixation of, other than for scoliosis, being a service associated with a service to which any one of items 48642 to 48675 applies – 1 to 4 levels (Anaes.) (Assist.)).
- The frequency of use of the four different interspinous non-fusion devices would be equal.

- The interspinous devices would be used in 95 per cent of patients, and the Dynesys device in 5 per cent of patients.

Table 49 shows the weighted average cost of insertion of non-fusion devices.

Table 47 MBS items associated with decompression and interspinous non-fusion devices (ie DIAM, Wallis, X STOP and Coflex)

Resource item	Cost	Percentage of patients	Source of data
Anaesthesia			
Anaesthesia initiation	\$137.20	100%	MBS item 20670
Time units 56 minutes – 1 hour ^a OR Time units 1:26–1:30 hours ^b	\$68.60 \$102.90	65% 35%	MBS item 23043 Estimated % of patients based on number of levels treated in the evidence base MBS item 23190 Estimated % of patients based on number of levels treated in the evidence base
Age modifier (over 70 years)	\$17.15	27%	MBS item 25015 % of patients based on age distribution of patients undergoing decompression—MBS 2005–06 statistics
Decompression surgery			
Laminectomy for 1 level of recurrent disc lesion or spinal stenosis OR Laminectomy for more than 1 level of spinal stenosis	\$943.65 \$1,243.05	65% 35%	MBS item 40303 Estimated % of patients based on number of levels treated in the evidence base MBS item 40306 Estimated % of patients based on number of levels treated in the evidence base
Spinal rhizolysis to expose nerve roots	\$826.50	100%	MBS item 40330 % of patients assumed for simplicity of analyses
Internal fixation with interspinous non-fusion devices			
Simple internal fixation of spine	\$489.35	100%	MBS item 48678
Assistance			
Assistance at operation	20% of surgery costs	100%	MBS item 51303
Intra-operative imaging			
Fluoroscopy for less than 1 hour OR Fluoroscopy for more than 1 hour	\$63.75 \$98.90	65% 35%	MBS item 60506 Estimated % of patients based on number of levels treated in the evidence base MBS item 60509 Estimated % of patients based on number of levels treated in the evidence base

MBS item costs from Medicare Australia; ^a estimated time of surgery on one vertebral level; ^b estimated time of surgery for two or more vertebral levels

Table 48 MBS items associated with decompression and the Dynesys

Resource item	Cost	Percentage of patients	Source of data
Anaesthesia			
Anaesthesia initiation	\$222.95	100%	MBS item 20670
Time units 2:51–3:00 hours ^a OR	\$240.10	65%	MBS item 23114 Estimated % of patients based on number of levels treated in the evidence base
Time units 4:21–4:30 hours ^b	\$394.45	35%	MBS item 23190 Estimated % of patients based on number of levels treated in the evidence base
Age modifier (over 70 years)	\$17.15	27%	MBS item 25015 % of patients based on age distribution of patients undergoing decompression—MBS 2005–06 statistics
Decompression surgery			
Laminectomy for 1 level recurrent disc lesion or spinal stenosis OR	\$943.65	65%	MBS item 40303 Estimated % of patients based on number of levels treated in the evidence base
Laminectomy for more than 1 level of spinal stenosis	\$1,243.05	35%	MBS item 40306 Estimated % of patients based on number of levels treated in the evidence base
Spinal rhizolysis to expose nerve roots	\$826.50	100%	MBS item 40330 % of patients assumed for simplicity of analyses
Internal fixation with Dynesys			
Segmental internal fixation – 1 or 2 levels OR	\$814.85	85%	MBS item 48684 Estimated % of patients based on number of levels treated in the evidence base
Segmental internal fixation – 3 or 4 levels	\$1,140.60	15%	MBS item 48687 Estimated % of patients based on number of levels treated in the evidence base
Assistance			
Assistance at operation	20% of surgery costs	100%	MBS item 51303
Intra-operative imaging			
Fluoroscopy for more than 1 hour	\$98.90	100%	MBS item 60509

MBS item costs from Medicare Australia; ^a estimated time of surgery on one vertebral level; ^b estimated time of surgery for two or more vertebral levels

Table 49 Calculations for weighted average cost of inserting the non-fusion devices

	1 level				2 or more levels			
	DIAM, Coflex, Wallis, X STOP		Dynesys		DIAM, Coflex, Wallis, X STOP		Dynesys	
	MBS item	cost	MBS item	cost	MBS item	cost	MBS item	cost
Anaesthesia								
100%	20670	\$137	20670	\$223	20670	\$137	20670	\$223
100%	23043	\$69	23114	\$240	23190	\$103	23190	\$394
27%	25015	\$5	25015	\$5	25015	\$5	25015	\$5
total		\$210		\$468		\$245		\$622
Surgery ^a								
100%	40303	\$944	40303	\$944	40306	\$1,243	40306	\$1,243
50%	40330	\$413	40330	\$413	40330	\$413	48687	\$570
25%	48678	\$122	48684	\$204	48678	\$122	40330	\$207
total		\$1,479		\$1,561		\$1,779		\$2,020
Assistant								
20% of surgery		\$296		\$312		\$356		\$404
Imaging	60506	\$64	60509	\$99	60509	\$99	60509	\$99
Total		\$2,049		\$2,439		\$2,478		\$3,144
Weighting ^b	0.6175		0.0325		0.3325		0.0175	
Weighted average	\$2,223							

^a When two or more operations are performed on the patient on one occasion, the schedule fee is as follows: 100% of most expensive item, 50% of next most expensive item, 25% of remaining items (Health Insurance Commission 2003); ^b weighting based on number of vertebral levels treated and equal usage of the interspinous devices, and assuming interspinous devices are used in 95% of non-fusion recipients (Table 42)

Prostheses

Decompression surgery

No prostheses are used for decompression surgery alone.

Decompression and fusion surgery

The cost components for fusion surgery are outlined in Table 50.

Table 50 Cost components of fusion prostheses

Components	Unit cost ^a	Cost for one level
Multi-axial screws (4 required for 1 level)	\$1,330 ^a	\$5,320
Set screws (4 required for 1 level)	\$155 ^a	\$620
Rods (2 required per level)	\$419 ^a	\$838
Posterior interbody cages (2 required per level) (used in 22.6% of patients) OR	\$3,581 ^{a, b}	\$7,162
Transverse interbody cages (1 required per level) (used in 3.4% of patients)	\$4,282 ^c	\$4,282
INFUSE® BMP-2 (used in 30% of patients) AND	\$6,400 ^a	\$6,400
Bone graft substitute (used in 30% of patients)	\$1,390 ^d	\$1,390

^a costs from Prostheses Register 2006; ^b cost of posterior interbody cages calculated from ratio of use of implanted cages; ^c average cost of transverse interbody cage from SPCAG database (Spinal Prostheses Clinical Advisory Group 2006); ^d based on the cost of Kainos granules, 20 cm³, from Prostheses Register 2006

The costing of the prostheses for fusion surgery assumes that all patients receive a pedicle screw system. Based on data received from Medtronic, approximately 30 per cent of patients who undergo fusion surgery also receive bone morphogenetic proteins (BMP). It is assumed that patients who receive BMP would also receive a bone graft substitute, and use 20 cm³ per vertebral level.

Posterior interbody or transverse interbody cages were used in 856 cases in 2005–06 (Spinal Prostheses Clinical Advisory Group 2006) from a total of 3,319 fusion procedures over the same period (Medicare Australia 2006). This equates to 26 per cent of patients who undergo fusion surgery receiving a cage. Transverse interbody cages are used in 13 per cent of cage recipients (95 cages used in a total of 716 procedures with cages in 2004–05) (Medicare Australia 2006; Spinal Prostheses Clinical Advisory Group 2006) so it is assumed that posterior interbody cages would be used in 87 per cent of patients who receive cages. The average cost per posterior interbody cage used in 2005–06 was \$3,581 (or \$7,162 per level), while the average cost of transverse interbody cages is \$4,282 per level (Spinal Prostheses Clinical Advisory Group 2006). Therefore, after applying the proportional usage, the average cost of interbody cages is \$6,788 per vertebral level.

Table 51 and Table 52 outline the weighted average costs of fusion prostheses per patient.

Table 51 Weighted average cost of fusion prostheses without interbody cages (74%)

Number of levels	Cost of fusion prostheses without BMP	Weighting ^a	Cost of fusion prostheses with BMP	Weighting ^a
1	\$6,778	0.455	\$14,568	0.195
2	\$10,586	0.14	\$19,766	0.06
3	\$14,394	0.07	\$24,964	0.03
4	\$18,202	0.035	\$30,162	0.015
Average cost per patient	\$11,439			

^a weighting based on expected number of levels treated (Table 42), with an expected 30% of patients receiving BMP; BMP = bone morphogenetic proteins

Table 52 Weighted average cost of fusion prostheses with interbody cages (26%)

Number of levels	Cost of fusion prostheses without BMP	Weighting ^a	Cost of fusion prostheses with BMP	Weighting ^a
1	\$13,556	0.455	\$21,356	0.195
2	\$24,162	0.14	\$33,342	0.06
3	\$34,758	0.07	\$45,328	0.03
4	\$45,354	0.035	\$57,314	0.015
Average cost per patient	\$21,956			

^a weighting based on expected number of levels treated (Table 42), with an expected 30% of patients receiving BMP; BMP = bone morphogenetic proteins

If the cost of prostheses is averaged across all patients who receive fusion surgery (weighted average from Table 51 and Table 52 after applying the proportional usage), the average cost per patient is \$14,173.

Non-fusion devices

Costs of the non-fusion devices were determined from the 2005 Prostheses List (with 2006 amendments) plus further information received from Zimmer Spine and Taylor Bryant, as listed in Table 53. As patients may receive non-fusion devices at more than one vertebral level, the weighted average costs of the non-fusion devices *per patient* have been calculated based on the number of levels expected to be treated (Table 42) and are displayed in Table 54. Due to the added cost and invasiveness of the Dynesys, it is anticipated that it would be used in only 5 per cent of patients. The assumption has been made that each interspinous device would receive equal utilisation. The cost of the devices would be covered by the States and Territories if inserted in a public patient in a public hospital, but by private health insurance or the individual if inserted in a private hospital.

Table 53 Costs of the lumbar non-fusion posterior stabilisation devices

Device	Company	Description	Cost ^a
Wallis	Orthotech	Non-Fusion Spine Stabilising Device (Titanium or PEEK)	\$4,990
X STOP	Global Manufacturing Technology	X Stop Interspinous Process Distraction (spacer assembly and wing assembly)	\$4,990
DIAM	Medtronic Australia	DIAM nuclear Sterile	\$4,313
Coflex	Taylor Bryant	Spine Motion COFLEX	\$3,700
Dynesys	Zimmer Spine	Total for one level:	\$8,650
		Dynesys spacer composition: polycarbonate (2 required per level)	\$600
		Dynesys pedicle screw composition: titanium alloy (4 required for 1 level)	\$1,200
		Dynesys cord composition: Sulene (2 cords per box, enough for 1 level)	\$2,650

^a costs derived from the Prostheses List 2005 (plus 2006 amendments), and Zimmer Spine and Taylor Bryant

Table 54 Weighted average cost of non-fusion devices per patient

Number of levels	Average cost of interspinous devices per patient	Weighting ^a	Cost of Dynesys devices per patient	Weighting ^a
1	\$4,498	0.6175	\$8,650	0.0325
2	\$8,996	0.19	\$12,250	0.01
3	\$13,994	0.095	\$15,850	0.005
4	\$18,492	0.0475	\$19,450	0.0025
Average cost per patient	\$7,226			

^a weighting based on expected number of levels treated (Table 42), assuming interspinous devices are used in 95% of non-fusion patients and Dynesys 5% of non-fusion patients

Hospital stay

Decompression surgery

The cost components of performing the decompression surgery in the private hospital system are outlined in Table 55. While the AR-DRG items I10A and I10B (other back and neck procedures, which are not specific to decompression surgery) were included, the DRGs are constructed according to clinical content and resource consumption. They are therefore used as the best estimate of the cost of decompression surgery.

The private hospital AR-DRG costs were used as the best estimate of hospital and theatre accommodation costs (Table 55). Excluding the costs associated with the

prostheses (which are not relevant to decompression surgery), the weighted average hospital and theatre accommodation costs (with and without complications or comorbidities) were therefore \$5,636.

Table 55 Average cost components for decompression in private hospitals

Charge component	I10 Other Back and Neck Procedures + CSCC	I10 Other Back and Neck Procedures – CSCC
Average LOS	11.5	5.47
No. of separations	505	5,853
Accommodation	\$5,547	\$2,795
Bundled	\$1,602	\$1,030
ICU	\$312	\$25
Other	\$212	\$100
Prostheses	\$694	\$466
Theatre	\$1,493	\$1,365
Total	\$9,861	\$5,795
Weighting ^a	0.08	0.92
Weighted average	\$6,118	

(Australian Government Department of Health and Ageing 2005); CSCC = complications or comorbidities; ^a weighting based on number of separations

Decompression and fusion surgery

The private hospital AR-DRG costs were used as the best estimate of hospital and theatre accommodation costs (Table 56). Excluding the costs of the prostheses, the weighted average cost of hospital stay for fusion surgery was \$8,925.

Table 56 Average cost components for fusion and decompression in private hospitals

Charge component	109A Spinal Fusion + CSCC	109B Spinal fusion – CSCC
Average LOS	13.6	7.72
No. of separations	437	1,997
Accommodation	\$6,648	\$4,032
Bundled	\$2,475	\$2,095
ICU	\$843	\$185
Other	\$237	\$183
Prostheses	\$11,693	\$8,197
Theatre	\$2,045	\$1,683
Total	\$23,942	\$16,392
Weighting ^a	0.18	0.82
Weighted average	\$17,748	

(Australian Government Department of Health and Ageing 2005); CSCC = complications or comorbidities; ^a weighting based on number of separations

Non-fusion devices

It was assumed that insertion of the interspinous devices (ie X STOP, Diam, Coflex and Wallis) would not extend the length of hospital stay longer than decompression alone would require. Therefore, the items I10A and I10B were used as the best estimate of hospital costs associated with the insertion of interspinous devices (ie \$5,636 per patient excluding medical practitioner and prostheses costs).

The Dynesys requires a more invasive procedure than the interspinous devices and it is the opinion of the Advisory Panel that, because of the surgical exposure required for the Dynesys, most spinal surgeons would opt for a standard fusion procedure rather than use a Dynesys device. The Advisory Panel determined that the AR-DRG items I09A and I09B were the best estimate of the costs of hospitalisation after insertion of the Dynesys pedicle screw system. The costs of hospitalisation are therefore expected to be \$8,925 per patient (excluding medical practitioner and prostheses costs) for patients receiving the Dynesys.

Since interspinous devices are assumed to be used 95 per cent of the time, and the Dynesys only 5 per cent, the average hospitalisation cost associated with non-fusion surgery is estimated to be \$5,800 per patient.

Summary of resources and incremental costs

The costs of performing the intervention and comparator procedures are derived from the costs of medical practitioner services, hospital and theatre accommodation costs, and prostheses costs.

The main comparison considered in this economic analysis is non-fusion devices plus decompression versus conventional surgery; and conventional surgery has been divided into two alternatives—decompression versus decompression plus fusion.

Insertion of a non-fusion device after decompression surgery adds a *further* \$7,561 per patient when compared to decompression surgery alone (Table 57). The majority of the extra cost (96%) comes from the device itself (\$7,226). Table 58 outlines the costs of decompression surgery with non-fusion devices and decompression and fusion surgery. Performing non-fusion surgery rather than fusion surgery is estimated to result in a cost *saving* of \$10,948 per patient. The majority of the cost saving (92%) is derived from the reduction in prostheses costs and reduced hospital and theatre accommodation costs.

Table 57 Summary of resources for non-fusion devices and decompression included in the economic evaluation

Resource items	Total weighted average cost		Incremental cost of proposed service
	Non-fusion and decompression	Decompression	
Medical practitioner services			
Anaesthesia	\$237 ^a	\$222 ^b	\$15
Surgery	\$1,591 ^a	\$1,462 ^b	\$129
Assistance	\$318 ^a	\$292 ^b	\$26
Imaging	\$77 ^a	\$76 ^b	\$1
Total medical practitioner services	\$2,223	\$2,052	\$171
Other costs			
Hospital and theatre accommodation	\$5,800 ^c	\$5,636 ^d	\$164
Prostheses	\$7,226 ^e	\$0	\$7,226
Total other costs	\$13,026	\$5,636	\$7,390
TOTAL COSTS	\$15,249	\$7,688	\$7,561

^a Medicare Benefits Schedule (Table 49); ^b Medicare Benefits Schedule (Table 44); ^c private hospital AR-DRG data, assuming 95% of patients receive interspinous devices (and therefore use costs from items I10A and I10B) and 5% of patients receive the Dynesys (and therefore use costs from items I09A and I09B) (Australian Government Department of Health and Ageing 2005) (Table 55 and Table 56); ^d private hospital AR-DRG data (Australian Government Department of Health and Ageing 2005) (Table 55); ^e derived from weighted average cost of prostheses (2005 Prostheses list, Zimmer Spine and Taylor Bryant (Table 54) assuming interspinous devices used in 95% of patients and weighted according to number of levels expected to be treated (Table 42)

Table 58 Summary of resources used for non-fusion devices and fusion with decompression included in the economic evaluation

Resource items	Total weighted average cost		Incremental cost of proposed service ^a
	Non-fusion and decompression	Fusion and decompression	
Medical practitioner services			
Anaesthesia	\$237 ^b	\$522 ^c	-\$285
Surgery	\$1,591 ^b	\$2,065 ^c	-\$474
Assistance	\$318 ^b	\$413 ^c	-\$95
Imaging	\$77 ^b	\$99 ^c	-\$22
Total medical practitioner services	\$2,223	\$3,099	-\$876
Other costs			
Hospital and theatre accommodation	\$5,800 ^d	\$8,925 ^e	-\$3,125
Prostheses	\$7,226 ^f	\$14,173 ^g	-\$6,947
Total other costs	\$13,026	\$23,098	-\$10,072
TOTAL COSTS	\$15,249	\$26,197	-\$10,948

^a negative results represent a cost saving; ^b Medicare Benefits Schedule (Table 49); ^c Medicare Benefits Schedule (Table 44); ^d private hospital AR-DRG data, assuming 95% of patients receive interspinous devices (and therefore use costs from items I10A and I10B) and 5% of patients receive the Dynesys (and therefore use costs from items I09A and I09B) (Australian Government Department of Health and Ageing 2005) (Table 55 and Table 56); ^e private hospital AR-DRG data (Australian Government Department of Health and Ageing 2005) (Table 56); ^f derived from weighted average cost of prostheses (2005 Prostheses list, Zimmer Spine and Taylor Bryant (Table 54) assuming interspinous devices used in 95% of patients and weighted according to number of levels expected to be treated (Table 42); ^g derived from weighted average cost of fusion prostheses with/without BMP, with/without interbody cages, based on benchmarking data and ratio of use of implanted cages (Table 51 and Table 52).

Weighted incremental cost

As there is no clear distinction between the patient populations who receive decompression alone or decompression plus fusion, the average cost of conventional surgery was determined using the weighted average cost of these two procedures (Table 59). The weighting was based on the expected uptake of the non-fusion devices.

The Advisory Panel estimated that 896–1,591 patients who currently receive decompression would be likely to receive non-fusion devices, and 269–538 patients who currently receive fusion surgery would be likely to receive non-fusion devices in private hospitals if Commonwealth funding was approved (for further explanation see ‘Financial incidence analysis’ section below). Using the midpoint of these estimates, the weighted average additional (incremental) cost of non-fusion devices compared with conventional surgery is therefore \$3,024 per patient.

Table 59 Weighted average incremental cost of non-fusion devices compared with conventional surgery

Estimate	Number of patients who are expected to receive non-fusion procedures		Weighted average incremental cost
	Decompression (\$7,561)	Decompression and fusion (-\$10,948) ^a	
Midpoint estimate	1,244	404	\$3,024
Upper estimate	1,591	269	\$4,884
Lower estimate	896	538	\$617

^a a negative cost indicates a cost saving

Financial incidence analysis

Expenditure by the Australian Government in a full year

Table 44 to Table 49 present the calculations for determining the weighted average expenditure per procedure. The weighted average cost of decompression surgery is \$2052, of performing decompression and fusion \$3,099, and of inserting one or more non-fusion devices \$2,223. Therefore, for every patient who receives a non-fusion device in addition to decompression rather than decompression surgery alone, there is an additional cost of \$171 to the MBS. However, for every patient who receives a non-fusion device rather than rigid instrumentation, there is an average *cost saving* of \$876 per patient.

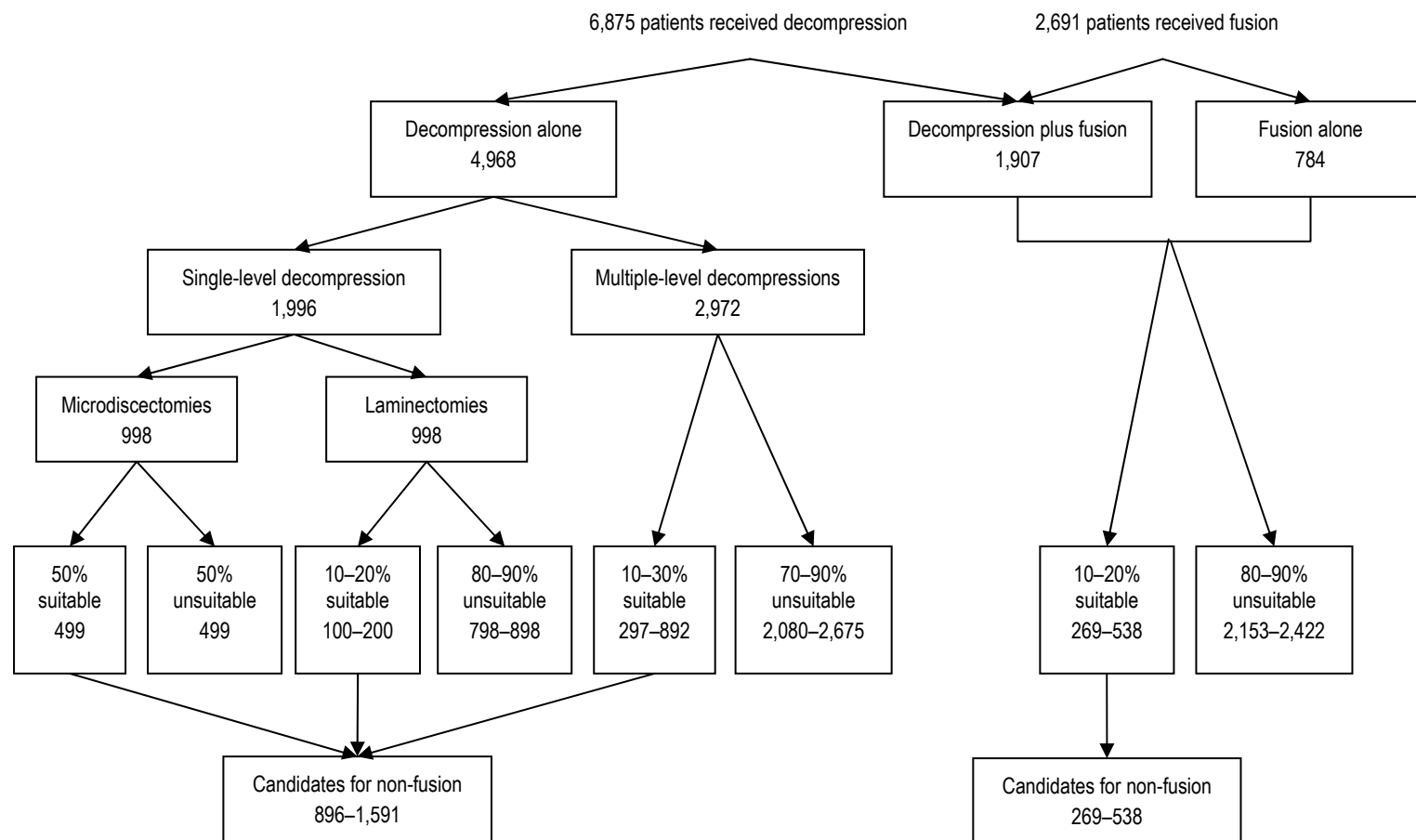
The direct financial implications to the Australian Government of subsidising lumbar non-fusion posterior stabilisation devices can be calculated by multiplying the expected per patient cost increase/saving by the likely uptake of the procedure in private hospitals.

The process of estimating the potential utilisation of non-fusion devices is outlined in Figure 9. There were 6,875 patients who received decompression procedures performed in private hospitals in Australia in 2005–06, and 2,691 patients who received posterior fusion procedures, of which 1,907 were performed concurrently with a laminectomy. Therefore, 4,968 patients received decompression procedures performed without fusion (1,996 at a single vertebral level and 2,972 at multiple levels).

Fifty per cent of single level decompressions would be performed for a repeat microdiscectomy. Of these 998 patients, the Advisory Panel suggests that 50 per cent would be candidates for non-fusion devices (ie 499 patients). The remaining 50 per cent of patients who receive single-level decompression would undergo laminectomy, and 10–20 per cent of these are suggested by the Advisory Panel to be candidates for non-fusion devices (100–200 patients). Similarly, it is estimated that 10–30 per cent of the 2,972 patients who receive multiple-level decompression would be candidates for non-fusion devices (297–892 patients). Therefore, there would be a total of 896–1,591 patients who currently receive decompression without fusion who may be candidates for non-fusion devices. The annual use of interspinous devices since 2004 is approximately 1,000 per year, which confirms the estimated figures shown above.

It is estimated by the Advisory Panel that between 10 and 20 per cent of patients who receive posterior fusion (with or without decompression) would be suitable for non-fusion devices. Therefore, it is expected that between 269 and 538 patients who currently receive fusion surgery would be candidates for non-fusion devices.

Figure 9 Estimated potential utilisation of non-fusion devices



There is a possibility that a small number of people with mild spinal stenosis who are not currently considered for surgery may receive an interspinous device. It is estimated that the cost to the Commonwealth of non-fusion surgery in these patients would be \$861 for one vertebral level and \$931 per patient for more than one vertebral level.

Table 60 shows that if receiving one or more non-fusion devices increases the cost of surgery over decompression by \$171, there could potentially be an *increase* in expenditure of \$153,216–\$272,061 by the Commonwealth Government. However, since fusion surgery is, on average, \$876 more expensive per patient, if 269–538 patients were to receive non-fusion rather than fusion surgery, there would be a *cost saving* of \$235,644–\$471,288. Therefore, the net impact to the Commonwealth is estimated to be between a *cost saving* of \$318,072 and a *cost increase* of \$36,417 per annum.

Table 60 Expenditure borne by the Australian Government in one full year

Resource items	Incremental cost of proposed service	Utilisation	Expenditure ^a
Decompression and non-fusion surgery versus decompression surgery			
Medical practitioner services	\$171 ^b	896–1,591	\$153,216 to \$272,061
Decompression and non-fusion surgery versus decompression and fusion surgery			
Medical practitioner services	–\$876 ^b	269–538	–\$235,644 to –\$471,288
Total			–\$318,072 to \$36,417

^a negative result indicates a cost saving; ^b estimated from the difference in costs of MBS items

Expenditure to the Australian healthcare system in a full year

The costs to the healthcare system overall include the costs to the Commonwealth Government (outlined above) plus the costs incurred to the States and Territories under the Australian Health Care Agreements (costs of performing the procedures in public hospitals, including hospital accommodation, prostheses etc).

Based on estimates made for the private hospital sector (Table 60), 896–1,591 patients would potentially receive the addition of non-fusion devices rather than decompression surgery alone, and 269–538 would receive non-fusion devices rather than fusion surgery. According to Australian Refined Diagnosis Related Group (AR-DRG) round 7 cost estimates, the public to private patient split for decompression and fusion surgeries is 29 per cent to 71 per cent. A majority of surgical procedures (71%) is therefore eligible for MBS reimbursement, whereas only a minority (29%) is covered by Australian Health Care Agreements between the states/territories and the Commonwealth. It is therefore estimated that, from the 4,837 fusion or decompression procedures performed in public hospitals (see ‘Burden of disease’ section, pg 18), 366–650 who would previously have received decompression surgery alone would be considered for an additional non-fusion device, and 110–220 who previously would have received fusion surgery (with/without decompression) would be considered for non-fusion surgery instead.

Table 61 outlines the additional expenditure borne by the States and Territories due to the expected utilisation of non-fusion devices.

Table 61 Expenditure borne by the States and Territories in one full year

Resource items	Incremental cost of proposed service	Utilisation	Expenditure ^a
Decompression and non-fusion surgery versus decompression surgery			
Medical practitioner services	\$171 ^b	366–650	\$62,586 to \$111,150
Hospital and theatre accommodation	\$164 ^b	366–650	\$60,024 to \$106,600
Prostheses	\$7,226 ^b	366–650	\$2,644,716 to \$4,696,900
Decompression and non-fusion surgery versus decompression and fusion surgery			
Medical practitioner services	–\$876 ^c	110–220	–\$96,360 to –\$192,720
Hospital and theatre accommodation	–\$3,125 ^c	110–220	–\$343,750 to –\$687,500
Prostheses	–\$6,947 ^c	110–220	–\$764,170 to –\$1,528,340
Total			\$358,766 to \$3,710,370

^a negative results indicate a cost saving; ^b see Table 57; ^c see Table 58

The costs to the health system overall include the expenditure borne by the Australian Government (Table 60) and the expenditure borne by the states and territories (Table 61). Therefore, it is estimated that the introduction of non-fusion devices for the lumbar spine would result in an additional cost to the Australian health system of between \$40,694 and \$3,673,953 per annum.

Expenditure borne by society in a full year

In the private healthcare system, the costs incurred fall on the health insurer, the patient or the MBS. Medicare Australia covers 75 per cent of the Schedule fee for the services and procedures provided. The individual and/or their health insurance covers the remaining 25 per cent of the Schedule fee (plus any gap between the fee charged and the Schedule fee) as well as the costs of hospital accommodation, theatre fees, prostheses and medicines.

Table 62 outlines the overall expenditure borne by patients and health insurance companies in Australia in 1 year with the expected utilisation of non-fusion devices.

Table 62 Expenditure borne by patients and private health insurance in one full year

Resource items	Incremental cost of proposed service	Utilisation	Expenditure ^a
Decompression and non-fusion surgery versus decompression surgery			
Hospital and theatre accommodation	\$171 ^b	896–1,591	\$153,216 to \$272,061
Prostheses	\$7,226 ^b	896–1,591	\$6,474,496 to \$11,496,566
Decompression and non-fusion surgery versus decompression and fusion surgery			
Hospital and theatre accommodation	–\$3,125 ^c	269–538	–\$840,625 to –\$1,681,250
Prostheses	–\$6,947 ^c	269–538	–\$1,868,743 to –\$3,737,486
Total			\$1,208,976 to \$9,059,259

^a negative results indicate a cost saving; ^b see Table 57; ^c see Table 58

The additional short-term costs of non-fusion devices are minimised when they are used as an alternative to fusion procedures, and are maximised when non-fusion devices are inserted in addition to decompression rather than decompression surgery alone. If 896 private patients and 366 public patients received non-fusion devices in addition to decompression surgery (lower estimates of utilisation), and 538 private patients and 220 public patients received non-fusion devices instead of fusion (upper estimates of

utilisation), the annual additional overall societal expenditure required is estimated to be \$1,249,670 (including costs claimed through the MBS, hospital and theatre accommodation, and prostheses). However, if 1,591 private patients and 650 public patients received non-fusion devices in addition to decompression surgery (upper estimates of utilisation), and 269 private patients and 110 public patients received non-fusion devices rather than fusion surgery (lower estimates of utilisation), the overall additional cost to society is estimated to be \$12,733,212. Therefore, the additional cost to society from non-fusion devices is estimated to be between \$1,249,670 and \$12,733,212.

Summary – Is lumbar non-fusion posterior stabilisation with/without decompression a cost-effective treatment option for patients with symptomatic lumbar spinal stenosis, degenerative spondylolisthesis, herniated disc or facet joint osteoarthritis (primarily with lumbar radicular compromise)?

There was not enough evidence on the effectiveness of non-fusion devices to perform a cost-effectiveness analysis. However, taking into account medical practitioner fees, hospital and theatre accommodation, and prostheses costs, a cost comparison, per patient, determined that inserting a non-fusion device is \$7,634 *more expensive* than a decompression procedure alone, and \$10,875 *cheaper* than fusion surgery.

Based on the expected utilisation of the non-fusion devices, the impact to the Commonwealth is estimated to be between a *cost saving* of \$318,072 and a *cost increase* of \$36,417 per annum.

Discussion

Dynesys

Is the Dynesys safe?

A total of eight studies reported on the safety of the Dynesys device. The Dynesys is the most invasive of the lumbar non-fusion posterior stabilisation devices, involving the insertion of pedicle screws.

Two small comparative studies (level III-3 interventional evidence) found that the Dynesys with decompression has a similar safety profile to decompression with/without fusion procedures. The majority of adverse events were minor and included dural lesions, infections, and some bone and device failures (screw loosening, breakage or device loosening). While any conclusions based on these results should be tentative due to the study limitations (ie the small number of participants, the average quality of the historical control studies and the lack of detail provided in the literature), the Dynesys appears to be as safe as decompression alone, and as safe as or safer than fusion with or without decompression.

It is hypothesised that malpositioning of implants would decrease with experience. Screw loosening also occurs after fusion surgery; however, there were no controlled trials included in this systematic review that reported on the comparative rates of screw loosening between the Dynesys device and fusion with instrumentation. In order to determine the comparative safety of the devices, further long-term controlled studies are required.

Some adverse events (such as adjacent segment instability and progression of spondylolisthesis) are likely to be a result of the natural history of degenerative disorders of the spine. The body of evidence is too inconsistent and limited to confidently state whether non-fusion devices are more effective than decompression and/or fusion at preventing these problems in adjacent vertebral segments.

There are several reasons why non-fusion stabilisation may be safer than the more invasive fusion procedures: 1) there is no need for bone harvesting and grafting; 2) the procedures are shorter to perform and have lower morbidity in terms of blood loss and infection; and 3) the procedures allow individual segments to be stabilised. However, the benefit of these factors has not been demonstrated in the literature to date.

Is the Dynesys effective?

Eight studies assessed the effectiveness of the Dynesys, of which only two provided comparative data. The best available evidence on the effectiveness of non-fusion devices was from two average-quality historical control studies (level III-3 evidence). One of the two studies (Putzier et al 2005) found that decompression surgery plus the Dynesys was as effective at reducing pain as decompression alone after 3 months, and more effective in the longer term (follow-up between 24 and 47 months). A small comparative study found that both the Dynesys and fusion surgery treatments were found to be effective at reducing pain, but fusion surgery provided greater pain relief at 14 months follow-up (Cakir et al 2003).

While the average pain in a group of patients may reduce, this is potentially due to large improvements in a small number of patients. It is therefore important to also know what proportion of patients improved as a result of the surgery. None of the studies on the Dynesys reported how many patients had a clinically important difference. Furthermore, it is unclear what effect the lack of blinding had on patients' self-perception of pain.

Two studies that assessed quality of life before and after non-fusion surgery found inconsistent results. One study found that decompression and Dynesys improved mean scores on the mental health, role emotional and vitality subscales of the short form – 36 (SF-36) questionnaire; however, the mean score on the general health subscale reduced after surgery. The historical control group (who received decompression and fusion surgery) improved on all the subscales.

Decompression plus the Dynesys was more effective than decompression and fusion surgery at improving patient-assessed functioning from baseline at 12 months follow-up (level III-3 evidence) (Cakir et al 2003). When functioning was assessed on the SF-36, decompression surgery plus the Dynesys improved patient functioning a similar amount to decompression plus fusion surgery (Cakir et al 2003). The other historically controlled study found no significant difference between decompression alone and decompression with the addition of the Dynesys, although both treatments showed significant benefits compared to baseline data (Putzier et al 2005).

Secondary outcomes such as length of hospital stay and rate of reoperation supported the use of the Dynesys compared to fusion surgery. Rates of reoperation were between 1.7–12.9 per cent at the index level after the Dynesys. While long-term data is not available comparing non-fusion devices with decompression with/without fusion surgery, data from Sweden, Finland and the United States report that the rate of reoperation 5–10 years after decompression surgery is 11–15 per cent (Malter et al 1998; Osterman et al 2003; Jansson et al 2005).

As the devices are intended to remain within the body for the lifetime of the patient, the follow-up periods in the included studies were too short to determine the long-term effectiveness of the different devices.

An overall evaluation of the body of evidence supporting the use of the Dynesys is provided in Table 63.

Table 63 Assessment of body of evidence for effectiveness of the Dynesys^a

Component	A Excellent	B Good	C Satisfactory	D Poor
Volume of evidence				Level IV studies, or level I to III studies with high risk of bias
Consistency			Some inconsistency reflecting genuine uncertainty around clinical question	
Clinical impact			Moderate	
Generalisability		Population(s) studied in the body of evidence is/are similar to the target population		
Applicability		Applicable to Australian healthcare context with few caveats		

^a See Table 6 for further information

While non-fusion stabilisation has been performed since 1986 (with the invention of the first generation of Wallis device), there are still no published randomised controlled trials comparing non-fusion devices with decompression and/or fusion surgery. There are several abstracts that have recently become available comparing the Dynesys with fusion but they only provide preliminary data. One further randomised trial, listed on the Current Controlled Meta-Register, compares the Dynesys against posterolateral fusion (Welch et al 2007). It is expected that, within several years, there will be comparative evidence that minimises risk of bias, allowing for firmer conclusions to be made on the comparative effectiveness of non-fusion stabilisation to decompression and/or fusion surgery.

X STOP

Is the X STOP safe?

Only two studies were included that assessed the X STOP. One study was a randomised controlled trial comparing the X STOP with non-operative treatment (which was deemed an inappropriate comparator due to the patient population having failed to respond to prior conservative treatment for 6 months). This study was therefore assessed as an uncontrolled study. With a total of 110 patients, the two included studies were not large enough to provide information on rare adverse events that may occur. From the included studies, the rate of complications from the X STOP was low, and blood loss was minimal from the procedure. One patient with a prior history of cardiovascular disease had pulmonary oedema 2 days after surgery, which resulted in death.

In addition to the safety benefits outlined for the Dynesys, the interspinous devices can be placed using a minimally invasive approach with less destruction of the soft tissue than fusion surgery.

Is the X STOP effective?

Clinically important improvements in pain levels were reported in 40–60 per cent of patients who received the X STOP device.

One good-quality single arm of a randomised controlled trial (level IV evidence) found that all subscales on the SF-36 significantly improved after insertion of an X STOP (Zucherman et al 2005). The mean improvements were small, so it remains unclear whether the benefits were clinically important.

Four uncontrolled studies found that 10–81 per cent of patients had a clinically significant improvement in functioning on the Zurich claudication questionnaire after the insertion of the X STOP. The largest improvements were found in the larger case series, possibly as a result of surgeon experience.

The volume of evidence on the X STOP was too small for a body of evidence matrix (similar to Table 63) to provide useful information.

Wallis

Is the Wallis safe?

No studies reporting on the safety of the *current* generation of Wallis device were identified, but one comparative study assessed the first generation of the Wallis. This non-randomised controlled trial found that there was no significant difference in the rate of minor adverse events between the Wallis implanted after a discectomy versus a discectomy alone. No major complications were reported for either treatment group.

Rate of reoperation was not significantly different between the Wallis and decompression.

Is the Wallis effective?

Only one study met the inclusion criteria for assessing the effectiveness of the Wallis device. This medium-quality non-randomised controlled trial (level III-2 evidence) found that the Wallis (inserted after a discectomy) was more effective than a discectomy alone at reducing pain, and at improving functioning, although the statistical or clinical significance of the improvements are unclear. While the results showed a potential benefit in patients receiving the Wallis device compared with a discectomy alone, the study only had a total of 40 patients in each treatment arm, so was not large enough to provide strong evidence on which to base conclusions.

Economic evaluation of lumbar non-fusion posterior stabilisation devices

The Advisory Panel was of the opinion that non-fusion devices were no less effective than, and as safe as, decompression and/or fusion procedures. When the incremental costs and savings are weighted according to the expected utilisation of non-fusion

devices, the average cost (from a societal perspective) is estimated to be an additional \$3,097 per patient. The cost of inserting non-fusion devices is an additional \$7,634 per person to the cost of decompression surgery alone but a cost saving of \$10,875 per patient compared to the cost of decompression and fusion surgery.

The financial incidence analysis found that Australian government subsidisation of lumbar non-fusion posterior stabilisation devices may result in between a cost *saving* of \$318,072 and an expenditure *increase* of \$36,417 per year to the Commonwealth government. The impact to the Australian healthcare system is estimated to be an expenditure increase of between \$83,472 and \$3,802,267 per year. This increase is predominantly due to the cost of the prostheses, which is borne by the States and Territories in public hospitals. The variation in costs is due to sensitivity analyses on the proportion of patients who receive non-fusion devices who would otherwise receive either decompression surgery or fusion surgery (with/without decompression).

Non-fusion interspinous devices provide an additional treatment option for a small number of patients with mild spinal stenosis, who previously may not have been considered for spinal surgery. Compared to conservative management, non-fusion devices have been found to reduce pain and improve quality of life (Zucherman et al 2004, 2005; Anderson et al 2006). The average cost to the Australian Government of non-fusion surgery in this population is estimated to be \$886 per patient.

Conclusions

Safety and effectiveness

The Dynesys is relatively safe and, based on a limited amount of short-term comparative evidence, appears as safe as decompression with/without fusion surgery. Limited evidence suggests that the X STOP is safe. There was no comparative information available to conclude whether the X STOP was as safe or as effective as decompression and/or fusion surgery. There was not enough evidence on the Wallis device to confidently determine whether it is as safe and effective as the comparative techniques. Preliminary results suggest that the Wallis may be as safe and as/or more effective than a discectomy alone in patients with herniated discs.

These devices appear effective at providing relief of post-operative leg pain and/or preventing post-operative back pain or worsening of back pain. There are inconsistencies in the literature regarding whether non-fusion devices are as, more, or less effective than fusion and/or decompression at reducing pain, or whether they are as or more effective at improving functioning than fusion and/or decompression. It is therefore concluded that non-fusion devices with/without decompression are no worse than decompression or fusion with/without decompression.

Economic evaluation

The financial incidence analysis estimated the impact on the Commonwealth Government to be between an expenditure *saving* of \$318,072 and an *increase* of \$36,417 per year. The additional cost to the Australian healthcare system per year is estimated to be between \$40,694 and \$3,673,953. The average additional cost to society per patient is \$3,024 when the costs and savings are weighted according to the expected uptake of non-fusion devices. Due to the benefits of interspinous devices over conservative management, a small number of patients with mild spinal stenosis, who may not otherwise have been considered for spinal surgery, are expected to receive non-fusion surgery. The cost to the Australian Government of surgery in this population is estimated to be \$886 per patient.

Recommendations

The MSAC has considered safety, effectiveness and cost-effectiveness for a pedicle screw device (Dynesys) and interspinous spacer devices compared with laminectomy with and without conventional spinal fusion.

Pedicle screw device (Dynesys)

Based on the limited evidence available for this device, the MSAC finds that the Dynesys is:

- as safe as laminectomy with spinal fusion, noting that, although there appears to be less blood loss with the use of Dynesys, there is a slightly higher incidence of loosening of the pedicle screws;
- no more effective in selected cases than laminectomy and fusion, and requires almost the same surgical exposure; and
- less cost-effective than laminectomy without fusion, and as cost-effective as laminectomy and spinal fusion.

The MSAC recommends that there is insufficient evidence to recommend a change in public funding arrangements for Dynesys at this time.

Interspinous spacers (X STOP, Wallis, Coflex, DIAM)

Based on the limited evidence available for these devices, the MSAC finds that interspinous spacer devices:

- are as safe as the conventional operations (if the devices were placed without laminectomy the risks and surgical exposure would be less than for conventional laminectomy);
- may be as effective in selected cases as laminectomy and fusion and may be associated with a better outcome in patients with limited or localised (single level) disc disease; and
- may be as cost-effective as laminectomy without fusion and more cost-effective than laminectomy and spinal fusion.

The MSAC recommends that there is insufficient evidence to recommend a change in the public funding arrangements for interspinous devices at this time.

The Minister for Health and Ageing accepted this recommendation on 20 May 2008.

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 to either 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
Dr Stephen Blamey (Chair)	general surgery
Professor Brendon Kearney (Deputy Chair)	health administration and planning
Associate Professor John Atherton	cardiology
Professor Syd Bell	pathology
Associate Professor Michael Cleary	emergency medicine
Associate Professor Paul Craft	clinical epidemiology and oncology
Ms Catherine Farrell	Department of Health and Ageing representative
Dr Kwun Fong	thoracic medicine
Dr David Gillespie	gastroenterology
Dr Debra Graves	medical administrator
Professor Jane Hall	health economics
Professor John Horvath	Department of Health and Ageing Chief Medical Officer
Associate Professor Terri Jackson	health economics
Associate Professor Frederick Khafagi	nuclear medicine
Dr Ray Kirk	health research
Associate Professor Donald Perry-Keene	endocrinology
Dr Ewa Piejko	general practice
Ms Sheila Rimmer	consumer health issues
Professor Ken Thomson	radiology
Dr Doug Travis	urology
Dr Mary Turner	Australian Health Ministers' Advisory Council representative
Dr David Wood	orthopaedics

Appendix B Advisory panel and evaluators

Advisory panel for MSAC application 1099 Lumbar non-fusion posterior stabilisation

Professor Ken Thomson (Chair) radiology	Member of MSAC
Ms Susan Liew orthopaedic surgery	Australian Orthopaedics Association nominee
Mr Quentin Malone neurological surgery	Royal Australasian College of Surgeons nominee
Mr Ian McPhee orthopaedic surgery	Australian Orthopaedics Association nominee
Dr Ross Taylor general practice	Royal Australian College of General Practitioners nominee
Ms Robin Toohey, AM consumer health	Consumer's Health Forum of Australia nominee
Dr David Wood orthopaedic surgery	Member of MSAC

Evaluators

Ms Skye Newton Research Officer	Adelaide Health Technology Assessment (AHTA), Discipline of Public Health, School of Population Health and Clinical Practice, University of Adelaide.
Ms Hedyeh Hedayati Research Officer	
Mr Thomas Sullivan Research Officer	
Ms Tracy Merlin Manager	
Mr John Moss Health Economist	
Professor Janet Hiller Director	

Appendix C Search strategies

Bibliographic databases used to identify literature

Electronic database	Time period
AustHealth	1997 – 4/2006
Cinahl	1994 – 4/2006
Cochrane Library – including, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, the Cochrane Central Register of Controlled Trials (CENTRAL), the Health Technology Assessment Database, the NHS Economic Evaluation Database	1994 – 4/2006
Current Contents	1994 – 4/2006
Embase.com (including Embase and Medline)	1994 – 4/2006
Pre-Medline	4/2006
ProceedingsFirst	1994 – 4/2006
Web of Science – Science Citation Index Expanded	1995 – 4/2006
EconLit	1994 – 4/2006

Other sources of evidence (1994 – 2/2006)

Source	Location
Internet	
NHMRC- National Health and Medical Research Council (Australia)	http://www.health.gov.au/nhmrc/
Australian Department of Health and Ageing	http://www.health.gov.au/
US Department of Health and Human Services (reports and publications)	http://www.os.dhhs.gov/
New York Academy of Medicine Grey Literature Report	http://www.nyam.org/library/greylit/index.shtml
Trip database	http://www.tripdatabase.com
Current Controlled Trials metaRegister	http://controlled-trials.com/
Health Technology Assessment International (HTAi)	http://www.htai.org/
International Network for Agencies for Health Technology Assessment	http://www.inahta.org/
National Library of Medicine Health Services/Technology Assessment Text	http://text.nlm.nih.gov/
National Library of Medicine Locator Plus database	http://locatorplus.gov
U.K. National Research Register	http://www.update-software.com/National/
Google scholar	http://scholar.google.com/
Websites of Health Technology Agencies	See Appendix D
Websites of Specialty Organisations	See Appendix D
Hand searching (Journals 2005–06)	
Spine	Library or electronic access
The Spine Journal	Library or electronic access
European Spine Journal	Library or electronic access
Expert clinicians	
Studies other than those found in regular searches	MSAC Advisory Panel
Pearling	
All included articles will have reference lists searched for additional relevant source material	

Search terms used

Area of inquiry	Search terms
Burden of disease	(('spine'/exp AND ('stenosis'/exp OR instability)) OR lss OR (herniat* AND (disc* OR disk*)) OR 'spondylolisthesis'/exp OR 'spondylarthrosis'/exp OR 'spondylolysis' OR (degenerative AND disc AND 'disease'/exp) OR (degenerative AND disk AND 'disease'/exp) OR (facet AND 'joint'/exp AND ('arthritis'/exp OR osteoarthritis)) OR 'lumbar disc hernia'/exp OR 'spine instability'/exp OR 'intervertebral disk degeneration'/exp) AND (prevalen* OR rate OR 'prevalence'/exp OR 'incidence'/exp) AND (('cross sectional' AND stud*) OR survey) AND [english]/lim AND [humans]/lim AND [1996-2006]/py
Safety, effectiveness and cost-effectiveness	('lumbar vertebrae'/exp OR 'lumbar spine'/exp OR 'spinal disease'/exp OR (spine* AND ('stenosis'/de OR instability)) OR lss OR (herniat* AND (disc* OR disk*)) OR 'spondylolisthesis'/de OR 'spondylarthrosis'/de OR (degenerative AND disc AND disease) OR (degenerative AND disk AND disease) OR (facet AND 'joint'/de AND arthritis) OR (modic AND i AND lesion) OR (static AND disorder) OR (facet AND arthropathy) OR 'lumbar disc hernia'/dm_su OR 'spine instability'/dm_su OR 'intervertebral disk degeneration'/dm_su OR 'intervertebral disc hernia'/dm_su OR 'spine surgery'/exp OR 'lumbar spine'/exp OR 'lumbar disk'/exp OR 'spine stabilization'/exp OR 'spine'/exp OR spin*) AND ((interspinous AND (implant* OR device* OR distract*)) OR ((dynamic OR elastic) AND (neutrali?ation OR stabili?ation)) OR 'non fusion' OR dynesys OR 'X STOP' OR (wallis AND system) OR (minns AND silicon) OR coflex OR (intervertebral AND assisted AND motion) OR diam OR fixano) AND [humans]/lim AND [1994-2006]/py

Appendix D Internet sites searched

Websites of health technology assessment groups

AUSTRALIA

- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) <http://www.surgeons.org/open/asernip-s.htm>
- Centre for Clinical Effectiveness, Monash University <http://www.med.monash.edu.au/healthservices/cce/evidence/>
- Health Economics Unit, Monash University <http://chpe.buseco.monash.edu.au>

AUSTRIA

- Institute of Technology Assessment / HTA unit <http://www.oeaw.ac.at/ita/e1-3.htm>

CANADA

- Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé (AETMIS) <http://www.aetmis.gouv.qc.ca/en/>
- Alberta Heritage Foundation for Medical Research (AHFMR) <http://www.ahfmr.ab.ca/publications.html>
- Canadian Coordinating Office for Health Technology Assessment (CCOHTA) http://www.ccohta.ca/entry_e.html
- Canadian Health Economics Research Association (CHERA/ACRES) – Cabot database <http://www.mycabot.ca>
- Centre for Health Economics and Policy Analysis (CHEPA), McMaster University <http://www.chepa.org>
- Centre for Health Services and Policy Research (CHSPR), University of British Columbia <http://www.chspr.ubc.ca>
- Health Utilities Index (HUI) <http://www.fhs.mcmaster.ca/hug/index.htm>
- Institute for Clinical and Evaluative Studies (ICES) <http://www.ices.on.ca>

DENMARK

- Danish Institute for Health Technology Assessment (DIHTA) http://www.dihta.dk/publikationer/index_uk.asp
- Danish Institute for Health Services Research (DSI) <http://www.dsi.dk/engelsk.html>

FINLAND

- FINOHTA <http://www.stakes.fi/finohta/e/>

FRANCE

- L'Agence Nationale d'Accréditation et d'Évaluation en Santé (ANAES) <http://www.anaes.fr/>

GERMANY

- German Institute for Medical Documentation and Information (DIMDI) / HTA <http://www.dimdi.de/en/hta/index.html>

THE NETHERLANDS

- Health Council of the Netherlands Gezondheidsraad <http://www.gr.nl/adviezen.php>

NEW ZEALAND

- New Zealand Health Technology Assessment (NZHTA) <http://nzhta.chmeds.ac.nz/>

NORWAY

- Norwegian Centre for Health Technology Assessment (SMM) <http://www.oslo.sintef.no/smm/Publications/Engsmdrag/FramesetPublications.htm>

SPAIN

- Agencia de Evaluación de Tecnologías Sanitarias, Instituto de Salud “Carlos III”/Health Technology Assessment Agency (AETS) <http://www.isciii.es/aets/>
- Catalan Agency for Health Technology Assessment (CAHTA) <http://www.aatm.es/cgi-bin/frame.pl/ang/pu.html>

SWEDEN

- Swedish Council on Technology Assessment in Health Care (SBU) <http://www.sbu.se/admin/index.asp>
- Center for Medical Health Technology Assessment <http://www.cmt.liu.se/English/Engstartsida.html>

SWITZERLAND

- Swiss Network on Health Technology Assessment (SNHTA) <http://www.snhta.ch/>

UNITED KINGDOM

- Health Technology Board for Scotland <http://www.htbs.org.uk/>
- National Health Service Health Technology Assessment (UK) / National Coordinating Centre for Health Technology Assessment (NCCHTA) <http://www.hta.nhsweb.nhs.uk/>
- University of York NHS Centre for Reviews and Dissemination (NHS CRD) <http://www.york.ac.uk/inst/crd/>
- National Institute for Clinical Excellence (NICE) <http://www.nice.org.uk/index.htm>

UNITED STATES

- Agency for Healthcare Research and Quality (AHRQ) <http://www.ahrq.gov/clinic/techix.htm>

- Harvard School of Public Health – Cost-Utility Analysis Registry <http://www.hsph.harvard.edu/cearegistry/>
- U.S. Blue Cross/ Blue Shield Association Technology Evaluation Center (TEC) <http://www.bcbs.com/consumertec/index.html>

Orthopaedic and spinal surgery websites

- American Academy of Orthopedic Surgeons (AAOS) <http://www.aaos.org/>
- American Association of Neurological Surgeons (AANS) <http://www.aans.org/>
- American College of Surgeons <http://www.facs.org/>
- American Orthopedic association <http://www.aoassn.org/>
- American Society for Bone and Mineral Research (ASBMR) <http://www.asbmr.org/>
- Asian-Australasian Society of Neurological Surgeons <http://www.aasns.com>
- Australian Society of Orthopaedic Surgeons (ASOS) <http://www.asos.org.au/>
- British Orthopaedic Association (BOA) <http://www.boa.ac.uk/>
- British Orthopaedic Research Society (BORS) <http://www.mech-eng.leeds.ac.uk/bors/intro.htm>
- Canadian Orthopaedic Association (COA) (also l'Association Canadienne d'Orthopédie) <http://www.coa-aco.org/>
- Congress of Neurological Surgeons (CNS) <http://www.neurosurgeon.org/>
- Cervical Spine Research Society (CSRS) <http://www.csrs.org/>
- International Society for the Study of the Lumbar Spine (ISSLS) <http://www.issls.org/>
- Neurosurgical Society of Australasia <http://www.nsa.on.net/>
- North American Spine Society (NASS) <http://www.spine.org/>
- Orthopedic Research Society (ORS) <http://www.ors.org/>
- Royal Australasian College of Surgeons (RACS) <http://www.racs.edu.au/>
- Royal College of Surgeons <http://www.rcseng.ac.uk/>
- Society of Neurological Surgeons <http://www.societyns.org/>
- Spine Society of Australia (SSA) <http://www.cms.uwa.edu.au/ssa/index.html>
- Western Orthopaedic Association (WOA) <http://www.woa-assn.org/>

Appendix E Critical appraisal checklists

Checklist for the critical appraisal of case series

Source: (Young & Ward 1999)

Title of review:

Title of study:

Author(s):

Year:

Comparators:

Score: /3

1. **Was the study conducted prospectively?** /1
 - Were the key outcomes measured before and after the intervention, using clear criteria defined *a priori*?

2. **Was the method of selection of cases identified and appropriate?** /1
 - Were patients selected consecutively or in an unbiased manner?
 - Was there evidence that the characteristics of the included cases were not significantly different from those of the treated population?

3. **Was the duration and completeness of follow-up reported and was it adequate?**
 - Are the number and characteristics of losses to follow-up presented? # /0.5
 - Are losses to follow-up managed by performing sensitivity analysis and/or including them in the final analysis? /0.5

Losses to follow-up >20% are unacceptable, particularly if unaccounted for.

Checklist for appraising the quality of intervention studies

Suitable for trials, cohorts and case-control studies assessing interventions

Source: Downs and Black (1998)–adapted for this MSAC assessment

Author(s):

Institution(s):

Year:

Study design:

Comparators:

Reporting

1. *Is the hypothesis/ aim/ objective of the study clearly described?*

yes	1
no	0

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*

If the main outcomes are first mentioned in the Results section, the question should be answered ‘no’.

yes	1
no	0

3. *Are the characteristics of the patients included in the study clearly described?*

In cohort studies and trials, inclusion and/or exclusion criteria should be given.

yes	1
no	0

4. *Are the interventions of interest clearly described?*

Interventions that are to be compared should be clearly described.

yes	1
no	0

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*

Possible confounders = age, body mass index, gender, smoking history, co-morbidities, medication

yes	2
partially	1
no	0

6. *Are the main findings of the study clearly described?*

Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions (This question does not cover statistical tests which are considered below).

yes	1
no	0

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*

In non-normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered ‘yes’.

yes	1
no	0

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
This should be answered ‘yes’ if the study demonstrates that there was a comprehensive attempt to measure adverse events.

Primary adverse events = death, infection, haemorrhage, increased pain, neurological symptoms, numbness, tingling, paralysis, loss of lordosis, myocardial infarction, pulmonary embolism, deep vein thrombosis
Secondary adverse events = device failure, kyphosis, device slip, device breakage, screw loosening

yes	1
no	0

9. *Have the characteristics of patients lost to follow-up been described?*
This should be answered ‘yes’ where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered ‘no’ where a study does not report the number of patients lost to follow-up.

yes	1
no	0

10. *Have the actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes, except where the probability value is less than 0.001?*

yes	1
no	0

External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*

The study must identify the source population for patients and describe how the patients

were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as ‘unable to determine’.

yes	1
no	0
unable to determine	0

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*

The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

yes	1
no	0
unable to determine	0

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*

For the question to be answered ‘yes’ the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered ‘no’ if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

yes	1
no	0
unable to determine	0

Internal validity—bias

14. *Was an attempt made to blind study subjects to the intervention they have received?*

For studies where the patients would have no way of knowing which intervention they received, this should be answered ‘yes’.

yes	1
no	0
unable to determine	0

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

yes	1
no	0
unable to determine	0

16. *If any of the results of the study were based on ‘data dredging’, was this made clear?*

Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer ‘yes’.

yes	1
no	0
unable to determine	0

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients?*
Where follow-up was the same for all study patients the answer should be ‘yes’. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be ‘yes’. Studies where differences in follow-up are ignored should be answered ‘no’.

yes	1
no	0
unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*

The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered ‘yes’. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were

appropriate and the question should be answered ‘yes’.

yes	1
no	0
unable to determine	0

19. *Was compliance with the intervention(s) reliable?*

Where there was non-compliance with the allocated treatment or where there was contamination of one group, the question should be answered ‘no’. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered ‘yes’.

yes	1
no	0
unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*

For studies where the outcome measures are clearly described, the question should be answered ‘yes’. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered ‘yes’.

yes	1
no	0
unable to determine	0

Internal validity—confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies) recruited from the same population?*

For example, patients for all comparison groups should be selected from the same hospital. The question should be answered ‘unable to determine’ where there is no information concerning the source of patients included in the study.

yes	1
no	0
unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies) recruited over the same period of time?*

For a study which does not specify the time period over which the patients were recruited, the question should be answered as ‘unable to determine’.

yes	1
no	0
unable to determine	0

23. *Were study subjects randomised to intervention groups?*

Studies which state that subjects were randomised should be answered ‘yes’ except where method of randomisation is unknown or would not ensure random allocation. For example, alternate allocation would score ‘no’ because it is predictable.

yes	1
no	0
unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*

All non-randomised studies should be answered ‘no’. If assignment was concealed from patients but not from staff, it should be answered ‘no’.

yes	1
no	0
unable to determine	0

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*

This question should be answered ‘no’ for trials if: the main conclusions of the study were based on analyses of treatment rather than intention-to-treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders

was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as ‘no’.

yes	1
no	0
unable to determine	0

26. *Were losses of patients to follow-up taken into account?*

If the number of patients lost to follow-up are not reported, the question should be answered as ‘unable to determine’. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered ‘yes’.

yes	1
no	0
unable to determine	0

Subscale Scores

Reporting = /11

External validity = /3

Bias = /7

Confounding = /6

Total Quality Index Score = /27

Power

27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*

a. Was there enough power to detect a difference of ..%, in the outcome '....'?

sample sizes – $n_1 =$; $n_2 =$

power =

Rank scoring for appraising the clinical importance of benefit/harm

Source: (NHMRC 2000)

Title of review:

Title of study:

Author(s):

Year:

Comparators:

Clinically important effect:

Rank score : /4

Ranking	Clinical importance of benefit/harm
1	A clinically important benefit for the full range of plausible estimates The confidence limit closest to the measure of no effect (the 'null') rules out a clinically unimportant effect of the intervention
2	The point estimate of effect is clinically important BUT the confidence interval includes clinically unimportant effects
3	The confidence interval does not include any clinically important effects
4	The range of estimates defined by the confidence interval includes clinically important effects BUT the range of estimates defined by the confidence interval is also compatible with no effect, or a harmful effect

Rank scoring for classifying the relevance of evidence

Source: (NHMRC 2000)

Title of review:

Title of study:

Author(s):

Year:

Comparators:

Rank score : /5

Ranking	Relevance of the evidence
1	Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival
2	Evidence of an effect on a surrogate outcome that has been shown to be predictive of patient-relevant outcomes for the same intervention
3	Evidence of an effect on proven surrogate outcomes but for a different intervention
4	Evidence of an effect on proven surrogate outcomes but for a different intervention and population
5	Evidence confined to unproven surrogate outcomes

Appendix F Excluded studies

Irrelevant population

Biomechanical studies

Caserta, S., La Maida, G.A. et al (2002). 'Elastic stabilization alone or combined with rigid fusion in spinal surgery: a biomechanical study and clinical experience based on 82 cases', *European Spine Journal*, 11, S192–S197.

Eberlein, R., Holzapfel, G.A. & Schulze-Bauer, C.A.J. (2002). 'Assessment of a spinal implant by means of accurate FE modeling of intact human intervertebral discs', Conference proceeding: World congress on computational mechanics (WCCM), Vienna, II-77, available at: <http://wccm.tuwien.ac.at/publications/Papers/fp80657.pdf>.

Eberly, J.H., Su, Q. et al (1999). 'Dynamic stabilization and the numerical evidence', Conference proceeding: International conference on multiphoton processes (ICOMP) VIII, Monterey, CA, pp. 129–136.

Garfin, S.R. & Mahar, A.S. (2005). 'The use of an interspinous implant in conjunction with a graded facetectomy procedure: Point of view', *Spine*, 30 (11), 1273–1274.

Lindsey, D.P., Swanson, K.E. et al (2003). 'The effects of an interspinous implant on the kinematics of the instrumented and adjacent levels in the lumbar spine', *Spine*, 28 (19), 2192–2197.

Irrelevant patient selection criteria

McKee, A., Oliver, M. et al (2003). 'Dynesys stabilisation for chronic back pain', Spine Society of Australia, Canberra, ACT, Australia.

Schiavone, A.M. & Pasquale, G. (2003). 'The use of disc assistance prostheses (DIAM) in degenerative lumbar pathology. Indications. Technique. Results', *Italian Journal of Spinal Disorders*, III (2), 215–220.

Taylor, J., Pupin, P. & Delajoux, S. 'Retrospective study of the clinical results of implanting a DIAM prosthesis', unpublished report by Société TERE0 for COUSIN-BIOTECH, France.

Irrelevant intervention

Graf

Askar, Z., Wardlaw, D. et al (2004). 'Correlation between inter-vertebral disc morphology and the results in patients undergoing Graf ligament stabilisation', *European Spine Journal*, 13 (8), 714–718.

Brechbuhler, D., Markwalder, T.M. & Braun, M. (1998). 'Surgical results after soft system stabilization of the lumbar spine in degenerative disc disease--long-term results', *Acta Neurochirurgica (Wien)*, 140 (6), 521–525.

Calatayud, V. (1998). 'Surgical results after soft system stabilization of the lumbar spine in degenerative disc disease - Long term results - Comment', *Acta Neurochirurgica*, 140 (6), 525.

Guigui, P. & Chopin, D. (1994a). '[Assessment of the use of the Graf ligamentoplasty in the surgical treatment of lumbar spinal stenosis. Apropos of a series of 26 patients]', *Revue du Chirurgie Orthopedique et Reparatrice de L'appareil Moteur*, 80 (8), 681–688.

Guigui, P. & Chopin, D. (1994b). 'The Graf flexible stabilization system in the treatment of lumbar spinal stenosis - A retrospective study of 26 patients', *Revue de Chirurgie Orthopedique et Reparatrice de L'appareil Moteur*, 80 (8), 681-688.

Hadlow, S.V., Fagan, A.B. et al (1998). 'The Graf ligamentoplasty procedure. Comparison with posterolateral fusion in the management of low back pain', *Spine*, 23 (10), 1172–1179.

Kanayama, M., Hashimoto, T. et al (2005). 'Non-fusion surgery for degenerative spondylolisthesis using artificial ligament stabilization - Surgical indication and clinical results', *Spine*, 30 (5), 588–592.

Markwalder, T. (1998). 'Surgical results after soft system stabilization of the lumbar spine in degenerative disc disease - Long term results - Author's reply', *Acta Neurochirurgica*, 140 (6), 525.

Markwalder, T.M., Dubach, R. & Braun, M. (1995). 'Soft system stabilization of the lumbar spine as an alternative surgical modality to lumbar arthrodesis in the facet syndrome. Preliminary results', *Acta Neurochirurgica (Wien)*, 134 (1–2), 1–4.

Markwalder, T.M. & Merat, M. (1994). 'The lumbar and lumbosacral facet syndrome - Diagnostic measures, surgical treatment and results in 119 patients', *Acta Neurochirurgica*, 128 (1–4), 40–46.

Markwalder, T. M. & Wenger, M. (2003). 'Dynamic stabilization of lumbar motion segments by use of Graf's ligaments: results with an average follow-up of 7.4 years in 39 highly selected, consecutive patients', *Acta Neurochirurgica*, 145 (3), 209–214.

Rigby, M.C., Selmon, G.P.F. et al (2001). 'Graf ligament stabilisation: mid- to long-term follow-up', *European Spine Journal*, 10 (3), 234–236.

Saxler, G., Wedemeyer, C. et al (2005). 'Follow-up study after dynamic and static stabilisation of the lumbar spine', *Zeitschrift fur Orthopadie und Ihre Grenzgebiete*, 143 (1), 92–99.

Sonntag, V. (1998). 'Surgical results after soft system stabilization of the lumbar spine in degenerative disc disease - Long term results - Comment', *Acta Neurochirurgica*, 140 (6), 525.

Fusion

Korovessis, P., Papazisis, Z. et al (2004). 'Rigid, semirigid versus dynamic instrumentation for degenerative lumbar spinal stenosis: a correlative radiological and clinical analysis of short-term results', *Spine*, 29 (7), 735–742.

Twinflex

Korovessis, P., Papazisis, Z. & Lambiris, E. (2002). 'The role of rigid vs. dynamic instrumentation for stabilization of the degenerative lumbosacral spine', *Studies in Health Technology and Informatics*, 91, 457–461.

Dynafix

Ribas, A. (2005). '136. Disc regeneration after posterior lumbar dynamic stabilization', *The Spine Journal*, 5, 71S.

DSS

Sengupta, D.K., Mulholland, R.C. et al. (2006). 'Prospective clinical study of dynamic stabilization with the DSS system in isolated activity related mechanical low back pain, with outcome at minimum 2-year follow-up', Global Symposium on Motion Preserving Technology, Montreal, Spine Arthroplasty Society.

Irrelevant outcomes

Bose, B. (2000). 'Improvement of cervical sagittal angulation using dynamic stabilization implant', Conference proceeding: Spinal surgery and related disciplines, Berlin, pp. 93–98.

Karadimas, E. (2005). 'Dynesys stabilisation system allows motion at the instrumented level: preliminary report on positional MRI findings of 25 cases', Conference proceeding: Spine Society of Australia, Auckland, NZ, 15–17 April 2005.

Karadimas, E., Nicol, M. et al (2005). 'P7. Dynesys stabilization system for the treatment of patients with discogenic low back pain', Conference proceeding: North American Spine Society, Philadelphia, PA, 5, 112S.

Siddiqui, M., Karadimas, E. et al (2005). 'P20. Positional MRI changes in the lumbar spine following insertion of a novel interspinous process distraction device', Conference Proceeding: North American Spine Society, Philadelphia, PA, 119S.

Siddiqui, M., Nicol, M. et al (2005). 'The positional magnetic resonance imaging changes in the lumbar spine following insertion of a novel interspinous process distraction device', *Spine*, 30 (23), 2677–2682.

Warlaw, D., Karamidas, E. et al (2005). 'Dynesys stabilization system as a treatment for discogenic low back pain: preliminary report on positional MRI findings of 25 cases.' Conference abstract: Global Symposium on Motion Preserving Technology, Spine Arthroplasty Society. New York, USA.

Irrelevant study design / not a study

(2005). 'Surgical treatment of the painful motion segment: Spine focus issue', *Spine*, 30 (16S), S1–78.

- Christie, S.D., Song, J.K. & Fessler, R.G. (2005). 'Dynamic interspinous process technology', *Spine*, 30 (16), S73–S78.
- Dinoi, L., Petrini, P. & Grimaldi, G. (2003). In XXVI Congresso Nazionale G.I.S., Rome, Italy (*excluded from effectiveness studies since it is not a before-and-after case series, and excluded from safety studies as no information*).
- Eichholz, D.M. & Fessler, R.G. (2006). 'Is the X STOP (R) interspinous implant a safe and effective treatment for neurogenic intermittent claudication?' *Nature Clinical Practice Neurology*, 2 (1), 22–23.
- Forzano, P. & Castagna, P. (1996). 'Procedures: DIAM a tool for the future', Conference proceeding: Simulation in industry, Genoa, Italy, pp. 169–174.
- Gunzberg, R. & Szpalski, R. (2003). 'The conservative surgical treatment of lumbar spinal stenosis in the elderly', *European Spine Journal*, 12 (Suppl 2), S176–S180.
- Huang, R. & Bertagnoli, R. (2005). 'Nonfusion technology in spinal surgery', - *Orthopedic Clinics of North-America*, 36 (3), xiii–xiv.
- Huang, R.C., Wright, T.M. et al (2005). 'Biomechanics of nonfusion implants', *Orthopedic Clinics of North America*, 36 (3), 271–280.
- Mariottini, A., Pieri, S. et al (2005). 'Preliminary results of a soft novel lumbar intervertebral prosthesis (DIAM) in the degenerative spinal pathology', In: *Advanced Peripheral Nerve Surgery and Minimal Invasive Spinal Surgery*, 92, Springer-Verlag Wien, Vienna, pp. 129–131 (*excluded from effectiveness studies since it is not a before-and-after case series, and excluded from safety studies as no information*).
- Markwalder, T.M. & Wenger, M. (2002). 'Adjacent-segment morbidity', *Journal of Neurosurgery*, 96 (1), 139–140.
- Mulholland, R.C. & Sengupta, D.K. (2002). 'Rationale, principles and experimental evaluation of the concept of soft stabilization', *European Spine Journal*, 11, S198–S205.
- Nockels, R. P. (2005). 'Dynamic stabilization in the surgical management of painful lumbar spinal disorders', *Spine*, 30 (16), S68–S72.
- Rehak, L. (2000). 'A device for the dynamic correction and stabilisation of spinal deformities', Conference proceeding: Spinal surgery and related disciplines, Berlin, 623–628.
- Schwarzenbach, O., Berlemann, U. et al (2005). 'Posterior dynamic stabilization systems: DYNESYS', *Orthopedic Clinics of North America*, 36 (3), 363–372.
- Senegas, J. (2002). 'Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: the Wallis system', *European Spine Journal*, 11, S164–S169.
- Sengupta, D. K. (2004). 'Dynamic stabilization devices in the treatment of low back pain', *Orthopedic Clinics of North America*, 35 (1), 43–56.

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Appendix G Study profiles of included studies

Study Location	Level of evidence (interventional) Quality	Study design	Study participants	Inclusion criteria / exclusion criteria	Procedure	Outcomes assessed	Length of follow-up
(Bordes-Monmeneu et al 2005) Spain	Level IV Quality: 2/3 Prospective Not stated if consecutive Follow-up complete	Uncontrolled before-and-after case series	94 patients 32 female, 62 male Mean age = 46.4 years Age range = 26–68 years 27 with primary disc hernia 54 cases with degenerative discopathy 13 with canal stenosis	<i>Inclusion</i> Disc degeneration, canal stenosis and instability <i>Exclusion</i> Not stated	<i>Intervention</i> Dynesys with or without prior discectomy at 1 or 2 levels <i>Comparator</i> N/A	<i>Safety</i> Primary: Adverse physical health outcomes <i>Effectiveness</i> Secondary: Patient assessed functioning (ODI)	Post-operative and 8–9 months
(Cakir et al 2003) Germany	Level III-3 Quality: 18/27 Reporting 9/11 External validity 1/3 Bias 5/7 Confounding 3/6	Historical control study	20 patients diagnosed with degenerative spinal stenosis accompanied by instability who completed 12 month-follow-up	<i>Inclusion</i> Claudicatio spinalis symptoms with lumbar spinal pain with/without pseudoradicular radiation An unsuccessful, conservative treatment over a period of at least 6 months Distinct improvement (>50%) on the basis of facet infiltration with a local anaesthetic in the segments intended for surgery <i>Exclusion</i> Not stated	<i>Intervention</i> Patients who underwent selective decompression surgery with dorsal dynamic stabilisation (Dynesys). Mean 1.6 (1–3) segments instrumented Mean 1.6 segments decompressed (1–3) <i>Comparator</i> Retrospective control: patients who had undergone selective decompression surgery with dorsoventral fusion Mean 1.4 segments fused (1–2) Mean 1.2 segments	<i>Safety</i> Primary: Adverse physical health outcomes <i>Effectiveness</i> Secondary: Hospital stay	Mean of 14.4 months

Study Location	Level of evidence (interventional) Quality	Study design	Study participants	Inclusion criteria / exclusion criteria	Procedure	Outcomes assessed	Length of follow-up
					decompressed (1–2)		
(Dubois 1999) France	Level IV Quality: 3/3 Prospective Consecutive Follow-up complete	Uncontrolled before-and-after case series	57 patients Mean age = 47 years Age range = 23–77 years	<i>Inclusion</i> Lumbar instabilities Low back pain due to pathologies of degenerative origin (determined by MRI or CT and functional X-ray in combination with clinical evaluation) <i>Exclusion</i> Not stated	<i>Intervention</i> Dynesys <i>Comparator</i> N/A	<i>Safety</i> Primary: adverse physical health outcomes <i>Effectiveness</i> Primary: patient-assessed pain secondary rate of reoperation analgesia usage	Mean = 13 months Range = 2–31 months
(Grob et al 2005) Switzerland	Level IV Quality: 1.5/3 Retrospective Consecutive Losses to follow-up not included in analyses	Uncontrolled before-and-after case series	31 patients Mean age = 50±13 years Age range = 30–80 years 23% had stenosis 35% had spondylosis 23% had disc degeneration 13% had failed back surgery 3% had degenerative listhesis 3% had extradural tumour	<i>Inclusion</i> Degenerative disease (disc/stenosis/spondylosis) resulting in some form of instability associated with neurogenic or radicular pain and/or chronic back pain <i>Exclusion</i> Not stated	<i>Intervention</i> Dynesys 42% with prior decompression of the spinal canal 1–4 levels treated <i>Comparator</i> N/A	<i>Safety</i> Primary: adverse physical health outcomes Secondary: device loosening <i>Effectiveness</i> Secondary: rate of reoperation patient-assessed functional status	Minimum of 2 years 30/31 patients followed up
(Lee et al 2004) Japan	Level IV Quality: 3/3 Prospective Consecutive Follow-up complete	Uncontrolled before-and-after case series	10 patients with LSS, who had preoperative leg pain with or without back pain Mean age = 71 years Age range = 61–79 years 3 female, 7 male	<i>Inclusion</i> Older than 60 years of age Have mild to moderate stenotic symptoms Have pain that is relieved when flexed and aggravated when extended Have dural sac compression in extension and relief in flexion as verified on dynamic MRI	<i>Intervention</i> X STOP surgery 1–2 levels treated (mean 1.1 levels) <i>Comparator</i> N/A	<i>Safety</i> Secondary: device failure <i>Effectiveness</i> Primary: patient-assessed pain Secondary: patient-assessed functional	9–18 months post-operatively Mean = 11 months

Study Location	Level of evidence (interventional) Quality	Study design	Study participants	Inclusion criteria / exclusion criteria	Procedure	Outcomes assessed	Length of follow-up
				<p><i>Exclusion</i></p> <p>unremitting pain in any position fixed motor deficit severe symptomatic LSS at 3 or more levels significant spinal instability</p>		status	
<p>(Putzier et al 2004)</p> <p>Likely overlap of population with Putzier, (2005)</p> <p>Germany</p>	<p>Level IV</p> <p>Quality: 1/3</p> <p>Not stated if prospective, but key outcomes measured before and after intervention</p> <p>Not stated if consecutive, but appear characteristic of the treated population</p> <p>Number of losses to follow-up not presented</p>	Uncontrolled before-and-after case series	<p>70 participants</p> <p>29 females, 41 males</p> <p>Mean age = 43 years</p> <p>Age range = 23–72 years</p>	<p><i>Inclusion</i></p> <p>Discomfort in the lumbar spine for at least 3 months which has not responded to conservative therapy</p> <p><i>Exclusion</i></p> <p>Absolute spinal stenosis</p> <p>Patients with conditions after decompressing and/or fusing interventions on the lumbar spine</p> <p>Pain greater than stage II</p> <p>Signs of osteoporosis or other metabolic bone diseases</p> <p>Presence of malignant tumours</p> <p>BMI > 30 kg/m²</p> <p>Chronic alcohol or drug abuse</p>	<p><i>Intervention</i></p> <p>Nucleotomy + Dynesys</p> <p>1–3 segments treated</p> <p><i>Comparator</i></p> <p>N/A</p>	<p><i>Safety</i></p> <p>Primary:</p> <p>adverse physical health outcomes</p> <p><i>Effectiveness</i></p> <p>Primary:</p> <p>patient-assessed pain</p> <p>Secondary:</p> <p>patient-assessed functional status</p>	Mean of 33 months (range = 18–50)
<p>(Putzier et al 2005)</p> <p>Germany</p>	<p>Level III-3</p> <p>Quality: 19/27</p> <p>Reporting 9/11</p> <p>External validity 2/3</p> <p>Bias 5/7</p> <p>Confounding 3/6</p>	Historical control study	<p>84 patients with symptomatic disc prolapse</p> <p>35 treated with Dynesys</p> <p>49 with nucleotomy</p>	<p><i>Inclusion</i></p> <p>MRI showed stage 1 disc degeneration</p> <p>Considerable morphological change of the ventral spinal column such as nucleus pulposus prolapse or re prolapse showing the alteration of at least 1 nerve root</p> <p>Clinical symptoms equivalent to a radicular syndrome</p> <p><i>Exclusion</i></p> <p>The following local</p>	<p><i>Intervention</i></p> <p>Dorsal dynamic stabilisation system (Dynesys) in addition to the minimally invasive nucleotomy</p> <p>1–2 segments treated</p> <p><i>Comparator</i></p> <p>Nucleotomy</p> <p>1–2 segments treated</p>	<p><i>Safety</i></p> <p>Primary:</p> <p>adverse physical health outcomes</p> <p><i>Effectiveness</i></p> <p>Primary:</p> <p>patient assessed pain</p> <p>Secondary:</p> <p>patient-assessed functional status</p>	Mean of 34 months (range = 24–47 months)

Study Location	Level of evidence (interventional) Quality	Study design	Study participants	Inclusion criteria / exclusion criteria	Procedure	Outcomes assessed	Length of follow-up
				<p>pathomorphological findings: epidural adhesions and/or periradicular fibrosis after precedent nucleotomy depicted on MRI, significant changes in the posterior section of the motion segment like marked facet joint arthritis, absolute spinal stenosis, spondylolisthesis, lumbar scoliosis >10° and stage II & stage III degenerative changes</p> <p>Pain greater than stage II</p> <p>Signs of osteoporosis or other metabolic bone diseases</p> <p>Presence of malignant tumours</p> <p>BMI>30 kg/m²</p> <p>Chronic alcohol or drug abuse</p>			
(Schnake et al 2006) Switzerland	Level IV Quality: 2.5/3 Prospective Consecutive Losses to follow-up low (8%) but not included in analyses	Uncontrolled before-and-after case series	26 patients 18 females, 8 males Mean age = 71 years Age range = 47–87 years 100% with leg pain while walking 81% with back pain 35% with paraesthesia at one or both legs	<p><i>Inclusion</i> Lumbar spinal stenosis and degenerative spondylolisthesis</p> <p><i>Exclusion</i> Not stated</p>	<p><i>Intervention</i> Dynesys with interlaminar decompression 1 level treated</p> <p><i>Comparator</i> N/A</p>	<p><i>Safety</i> Primary: adverse physical health outcomes Secondary: radiographic outcomes</p> <p><i>Effectiveness</i> Primary: patient assessed pain Secondary: analgesia usage</p>	Minimum = 24 months Mean = 26 months
(Senegas 2002) France	Level III-2 Quality: 18/27 Reporting 8/11 External validity 2/3 Bias 5/7 Confounding 3/6	Non-randomised controlled trial	80 patients <i>Intervention</i> 11 women, 29 men Mean age = 42 years Age range = 25–62 years 50% motor deficit	<p><i>Inclusion</i> Participants who underwent surgery for recurrence of herniated disc after an initial L4–L5 discectomy</p> <p><i>Exclusion</i> Not stated</p>	<p><i>Intervention</i> Discectomy and implantation of first generation Wallis</p> <p><i>Comparator</i> Second discectomy</p>	<p><i>Safety</i> Primary: Adverse physical health outcomes</p> <p><i>Effectiveness</i> Primary: patient-assessed pain</p>	Mean = 3 years and 4 months (range = 1 year – 4 years, 8 months)

Study Location	Level of evidence (interventional) Quality	Study design	Study participants	Inclusion criteria / exclusion criteria	Procedure	Outcomes assessed	Length of follow-up
			<i>Comparator</i> 14 women, 26 men Mean age = 41 years Age range = 22–58 years 30% motor deficit		alone	(VAS) Secondary patient-assessed functioning (ODI)	
(Stoll et al 2002b) Switzerland	Level IV Quality: 2.5/3 Prospective Consecutive Follow-up adequate (88%) but losses to follow-up not included in analyses	Uncontrolled before-and-after case series	83 patients Mean age = 58.2 years Age range = 26–85 years 49 female, 34 male 50 with spinal stenosis 20 with degenerative discopathy 7 with disc herniation 5 with revision surgery 39 with degenerative spondylolisthesis 30 with previous therapeutic lumbar interventions	<i>Inclusion</i> Neurogenic, radicular pain and/or chronic low back pain resistant to any conservative treatment, presenting with some form of instability, where stabilisation was judged to be beneficial <i>Exclusion</i> Not stated	<i>Intervention</i> Dynesys Decompression in 69% Nucleotomy in 4% 1–4 levels treated (mean 1.5 levels) <i>Comparator</i> N/A	<i>Safety</i> Primary: adverse physical health outcomes Secondary: loose screws <i>Effectiveness</i> Primary: patient-assessed pain (VAS) Secondary: rate of reoperation patient-assessed functional status (ODI)	Mean = 38 months Range = 11–79 months 73/83 patients
(Zucherman et al 2004) (Zucherman et al 2005) Unites States	Level IV Quality: 2.5/3 Prospective Selection unbiased Follow-up adequate (93%) but excluded outcomes from those patients unable to be followed up	Single arm of a randomised controlled trial	100 neurogenic intermittent claudication patients 136 levels Mean age = 69.9 years 35 with spondylolisthesis 43 female, 57 male	<i>Inclusion</i> At least 50 years old Have leg, buttock or groin pain with or without back pain that was relieved during flexion More moderate symptoms of neurogenic intermittent claudication Ability to walk at least 50 feet <i>Exclusion</i> Patients could not have: a fixed motor deficit Cauda-equina syndrome	<i>Intervention</i> Surgery for implantation of the X STOP device 1–2 levels <i>Comparator</i> Non-operative treatment, which is not the included comparator; therefore, information on the patients treated with the	<i>Safety</i> Primary: adverse physical health outcomes <i>Effectiveness</i> Primary: patient-assessed pain Secondary: patient-assessed functional status	6 weeks, 6 months, 1 year and 2 years following treatment

Study Location	Level of evidence (interventional) Quality	Study design	Study participants	Inclusion criteria / exclusion criteria	Procedure	Outcomes assessed	Length of follow-up
				previous lumbar surgery of the stenotic level, or spondylolisthesis greater than grade I on a scale of I to IV at the affected level(s)	comparator is not included and this study is treated as a case series		

TIS = treatment intensity score; LSS = lumbar spinal stenosis; NASS = North American Spine Society lumbar outcome assessment; QOL = quality of life; SF-36 = short form - 36; VAS = visual analogue scale; DDD = degenerative disc disease; ODI = Oswestry disability index; MRI = magnetic resonance imaging; DIAM = Device for Intervertebral Assisted Motion; BMI = body mass index; JOA = Japanese Orthopaedic Association scale; N/A = not applicable; ZCQ = Zurich claudication questionnaire

Glossary

ALIF	anterior lumbar interbody fusion
Arthroplasty	surgery to relieve pain and restore range of motion by realigning or reconstructing a joint
BMP	bone morphogenetic proteins
Claudication	symptoms of leg pain or weakness and limping that are present when walking but absent at rest
Decompression	surgery which removes tissue to release a compressed nerve; types of decompression include: laminectomy, laminotomy, laminoplasty, foramenotomy, anterior discectomy
DIAM	Device for Intervertebral Assisted Motion
Discectomy	removal of all or part of an intervertebral disc
Extension	moving a joint towards straightness
Facet arthrosis	chronic degeneration of the facet joint cartilage and enlargement of the bony aspects (articular processes) of the joint
Flexion	the bending of a joint or the act of being bent
JOA	Japanese Orthopaedic Association
Kyphosis	abnormal rearward curvature of the spine, resulting in protuberance of the upper back; hunchback
Laminectomy	surgical removal of part of a vertebra, usually done to relieve pressure on a spinal nerve caused by a herniated disk or bony spur
Laminotomy	an operation to remove part of the lamina to allow more room for the spinal cord and nerves
LSS	lumbar spinal stenosis
L	lumbar
MBS	Medicare Benefits Schedule
Motion segment	consists of two adjacent vertebrae, including the intervertebral disk between them and the ligaments that bind them together
MSAC	Medical Services Advisory Committee

NASS	North American Spine Society
NHMRC	National Health and Medical Research Council
NHS	National Health Service (United Kingdom)
ODI	Oswestry disability index
OECD	Organisation for Economic Cooperation and Development
PEEK	Polyetheretherketone
PLIF	posterior lumbar interbody fusion
Posterior spinal Radiculopathy	includes the facet joints, spinal canal and foramen elements the irritation of a nerve root at any level of the spine
RR	relative risk or rate ratio
S	sacral
Sacralisation	incomplete separation and differentiation of the fifth lumbar vertebra (L5) such that it takes on characteristics of a sacral vertebra
Scoliosis	abnormal lateral curvature of the spine
SF-36	short form – 36 questionnaire
Spinal stenosis	a narrowing of the lumbar (back) or cervical (neck) spinal canal which causes compression of the nerve roots
Spondylolisthesis	the forward displacement of one vertebra on its lower neighbour
Spondylarthrosis	hypertrophy of the intervertebral joints
VAS	visual analogue (pain) scale
ZCQ	Zurich claudication questionnaire (otherwise known as Swiss spinal stenosis questionnaire)

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