Title:	Lumbar non-fusion posterior stabilisation devices
Agency:	Medical Services Advisory Committee (MSAC) MDP 106 Commonwealth Department of Health and Ageing GPO Box 9849 Canberra ACT 2601 http://www.msac.gov.au
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Aim:
To evaluate the safety, effectiveness, and cost considerations associated with lumbar non-fusion posterior stabilisation devices. These 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.

Results and Conclusions:
Safety:
Pedicle screw device (Dynesys)
Based on results from two historically controlled studies and six case series, the Dynesys appears to be as safe as decompression surgery alone or in combination with fusion surgery. Major complications such as malpositioning of pedicle screws and pedicle fractures occurred in a median of 5 per cent of patients. Loosening of screws occurred in up to 16.7 per cent of patients.
Interspinous spacers (X STOP, Wallis, Coflex, DIAM)
The number of complications reported was related to the invasiveness of the procedure. Interspinous devices are less invasive than the Dynesys or fusion surgery, and were associated with less blood loss. One study reported a similar frequency of minor complications after insertion of an interspinous device as from decompression alone.

Effectiveness:
Pedicle screw device (Dynesys)
One historically controlled study reported that the Dynesys was as effective at reducing pain as decompression alone, while another study reported that spinal fusion was slightly more effective at reducing pain, although the statistical and clinical significance of this difference is unclear. The Dynesys was as, or more, effective at improving functioning than fusion surgery. The Advisory Panel concluded that non-fusion devices are of equal clinical effectiveness to that of decompression with or without fusion surgery.

Interspinous spacers (X STOP, Wallis, Coflex, DIAM)
Only one comparative study assessing interspinous non-fusion devices was identified. It reported that these devices may be slightly more effective at reducing pain and improving functioning than decompression surgery alone. The re-operation rate was similar.

Cost considerations:
There was insufficient information on which to base a cost-effectiveness analysis. Non-fusion devices were estimated to cost $7,634 more per person than decompression surgery alone, and $10,875 less per person than fusion surgery. There is a large degree of uncertainty around how many patients would likely receive non-fusion devices if they were funded, and the treatment these patients would otherwise have received.
The estimated overall financial impact to the Commonwealth, States and Territories of funding non-fusion devices therefore ranged between $83,472 and $3,802,267 per annum.

Recommendations:
The MSAC has considered the safety, effectiveness and cost-effectiveness of a pedicle screw device (Dynesys) and of interspinous spacer devices compared to 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;
is no more effective in selected cases than laminectomy and fusion, and requires almost the same surgical exposure; and
is 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 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 endorsed this recommendation on the 20th May 2008.

Method:
Medline, Embase, The Cochrane Library, and several other biomedical databases, HTA and other internet sites were searched (1996- April 2006). Specific journals were handsearched and reference lists pearled. Studies were assessed for inclusion in the review using pre-determined PICO selection criteria and reasons for exclusion were documented. Study quality was appraised, data extracted in a standardised manner, and findings synthesised narratively.