

<b>Title:</b>	<b>Review of interim funded service: Artificial intervertebral disc replacement - lumbar</b>
<b>Agency:</b>	Commonwealth Department of Health and Ageing GPO Box 9848 Canberra ACT 2601 on behalf of the Medical Services Advisory Committee (MSAC) <a href="http://www.msac.gov.au">http://www.msac.gov.au</a>
<b>Assessment Group:</b>	Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) and Centre for Health Economics Research and Evaluation (CHERE)
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### **Aim**

To assess the safety, effectiveness and cost-effectiveness of lumbar artificial intervertebral disc replacement (AIDR) for the treatment of patients suffering from significant axial back pain and/or radicular pain, secondary to disc degeneration or prolapse, who have failed nonoperative treatment.

### **Results and Conclusions**

#### ***Safety***

A total of 43 studies were identified for inclusion in the assessment of the safety of lumbar AIDR. This included five comparative studies and 38 case series. Comparative studies compared lumbar AIDR with lumbar fusion procedures. Sample sizes ranged from 10 to 427 patients, with safety data reported for an overall total of 3,224 patients.

For the majority of adverse events reported, there were no obvious differences in incidence rates between the lumbar AIDR and lumbar fusion groups, with two studies reporting no statistical differences in the rate of overall complications between the two groups. Wound infection was the most commonly reported adverse event, and demonstrated an incidence rate of 3.2 per cent in the lumbar AIDR population, and 5.1 per cent in the lumbar fusion population. Prosthesis-related adverse events were those relating to movement of the device, including collapse or subsidence (3%), and displacement (0.78%). Fusion-related adverse events included nonunion/pseudarthrosis (6.4%) and bone graft donor-site pain (11.1%). The rate of adjacent segment problems appeared higher following lumbar fusion (8.3%) compared with lumbar AIDR (1.3%). Major adverse events such as major vessel injury, and neurological damage including nerve root injury were rare in both the lumbar AIDR and fusion groups. There was one reported death following lumbar AIDR which was narcotic-related, while no deaths were reported following lumbar fusion.

Overall, the safety of lumbar AIDR is comparable to that of lumbar fusion. It appears that the lumbar AIDR procedure is relatively safe, and is not associated with serious adverse events.

#### ***Effectiveness***

A total of 13 comparative studies were identified and included to inform on the comparative effectiveness of lumbar AIDR, including a total of four RCTs (comprising 12 studies) that compared lumbar AIDR to anterior lumbar interbody fusion (ALIF), circumferential fusion, or posterolateral fusion/posterior lumbar interbody fusion (PLF/PLIF), as well as one nonrandomised comparative study that compared lumbar AIDR to ALIF.

All of the included comparative studies utilised the Oswestry Disability Index (ODI), one of the principal condition-specific measures used in the management of spinal disorders, and the gold standard for assessing the extent to which a patient's functional level is limited by low back pain. Three studies reported that patients in the lumbar AIDR group showed statistically greater improvements in ODI scores than lumbar fusion patients at various time points up to 1-year follow-up; however, none of the studies reported significant differences between the groups at 2- or 5-year follow-up. Similarly, two studies reported that at 2-year follow-up overall clinical success was significantly higher in the lumbar AIDR group compared with the lumbar fusion group, while the rate of reoperation was similar in both groups. In two studies, patient satisfaction at 2-year follow-up was significantly higher in lumbar AIDR patients compared with lumbar fusion patients, with up to 81 per cent of AIDR patients saying they would have the procedure again,

compared with 69 per cent of fusion patients. This may have reflected the fact that lumbar AIDR patients experienced significantly less pain and required less narcotic medication, reported better sexual function, and returned to work at higher rates, when compared with lumbar fusion patients up to 2 years after surgery. Radiographic outcomes were reported in several studies; however, outcomes were reported differently across studies, and no statistical comparisons between the lumbar AIDR and lumbar fusion groups were reported, making it difficult to draw firm conclusions.

Overall, in the short to medium term the effectiveness of lumbar AIDR, in terms of ODI scores, success of the procedure, pain, patient satisfaction, workstatus, quality of life and sexual function, appears to be comparable to lumbar fusion procedures.

### ***Cost-effectiveness***

The economic evaluation adopted a cost-effectiveness analysis and a cost-utility analysis framework. For AIDR compared to fusion the incremental costs, incremental costs per patient discontinuing narcotic medication at 2 years, incremental costs per additional overall clinical success at 2 years and incremental costs per additional ODI success at 2 years were presented. For AIDR compared to PLF/PLIF the incremental cost per quality-adjusted life year (QALY) gained was presented. This mixed approach was undertaken due to uncertainty about the outcome of most clinical relevance and whether the results were statistically significant.

The incremental costs associated with each procedure demonstrate that compared to PLIF, combination and circumferential fusion, AIDR is cost saving. Compared to ALIF, AIDR is marginally more expensive. Overall, compared to the average fusion cost, AIDR represents a cost saving of \$1,600 per patient.

AIDR was both less costly and more effective than lumbar fusion overall for patients discontinuing narcotic medication and in terms of overall success. In terms of ODI success, AIDR was both less costly but less effective than lumbar fusion overall. The incremental cost per additional patient achieving ODI success was estimated to be \$126,191 with lumbar fusion compared to AIDR.

The results varied considerably by fusion approach. AIDR was more costly but achieved a higher rate of patients discontinuing narcotic medication, overall success and ODI success than ALIF. The incremental cost per additional patient discontinuing narcotic medication, achieving overall success, and achieving ODI success with AIDR compared to ALIF was estimated to be \$46,439, \$20,433 and \$34,883, respectively. AIDR was less effective in terms of ODI success compared to PLIF and PLF. PLF was also less costly and thus PLF was considered to dominate AIDR. PLIF was more costly and the incremental cost per additional patient achieving ODI success with PLIF was estimated to be \$35,373. AIDR was both less costly and more effective than circumferential fusion for all measures of efficacy. Therefore AIDR is considered to dominate circumferential fusion.

PLIF and PLF were estimated to be more effective in terms of QALYs gained compared to AIDR. PLF was also less costly and thus PLF was considered to dominate AIDR. The cost per QALY gained was estimated to be \$598,794 with PLIF.

Overall the results were most sensitive to using the direct approach to apply utility weights, changes in the relative risk of overall or ODI success and the time in hospital with AIDR. The results were somewhat sensitive to the proportion of fusion patients requiring bone morphogenetic protein (BMP). When hospitalisation costs with AIDR were assumed to be equal to that with fusion, fusion became less costly compared to AIDR. If a direct approach were used to apply utility weights, the average QALYs gained with lumbar AIDR and PLIF/PLF was 1.25 QALYs and 1.16 QALYs, respectively. Thus QALYs experienced increased by 0.10 QALYs with lumbar AIDR compared to PLIF/PLF. Using this approach AIDR was estimated to be less costly and more effective compared to PLIF. While compared to PLF, AIDR was estimated to be more costly and more effective, and had an additional cost per QALY of \$8,443.

### **Methods**

The evidence regarding the use of lumbar AIDR for the treatment of patients suffering from significant axial back pain and/or radicular pain, secondary to disc degeneration or prolapse, was systematically assessed. PubMed, EMBASE and the Cochrane Library were searched for relevant literature from January 2005 to April 2010. Studies were included in the review using pre-determined PICO selection criteria and reasons for exclusion were documented. The quality of studies was assessed, data were extracted in a standardised manner, and results were reported narratively.