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**Department of Health and Ageing**



Australia and New Zealand Horizon Scanning Network

**ANZHSN**

AN INITIATIVE OF THE NATIONAL, STATE AND  
TERRITORY GOVERNMENTS OF AUSTRALIA  
AND THE GOVERNMENT OF NEW ZEALAND

# **Horizon Scanning Technology Prioritising Summary**

## **Transaxial Anterior Lumbar Interbody Fusion**

**April 2010**



**Australian  
Safety  
and Efficacy  
Register  
of New  
Interventional  
Procedures -  
Surgical**



**Royal Australasian  
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# PRIORITISING SUMMARY

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**REGISTER ID** S000106

**NAME OF TECHNOLOGY** TRANSAXIAL ANTERIOR LUMBAR INTERBODY FUSION (AXIALIF™).

**PURPOSE AND TARGET GROUP** PATIENTS WITH BACK PAIN IN WHOM FIXATION OF THE LOWEST LUMBAR VERTEBRA TO THE SACRUM IS CONSIDERED.

## STAGE OF DEVELOPMENT (IN AUSTRALIA)

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established  |
| <input type="checkbox"/> Experimental             | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational          | <input type="checkbox"/> Should be taken out of use   |
| <input type="checkbox"/> Nearly established       |   |

## AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes  
 No  
 Not applicable

## INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or completed	Limited Use	Widely Diffused
Brazil	✓		
Italy	✓	✓	
Ireland			
Japan	✓		
United Kingdom		✓	
United States		✓	

## IMPACT SUMMARY

Transaxial anterior lumbar interbody fusion is a minimally invasive spinal fusion procedure used to treat patients with chronic lower back pain. This procedure offers an alternative to traditional fusion techniques that utilise anterior or posterior approaches to directly expose the lumbosacral spine. In the case of transaxial anterior lumbar interbody fusion the lumbosacral spine is accessed percutaneously via the anterior surface of the sacrum.

## **BACKGROUND**

Lower back pain, neck pain and related spinal disorders are prevalent in industrialised countries and have a variety of aetiologies (Ledet et al 2006). Back pain may originate in paraspinal muscles, facet joints, spinal ligaments, failed endplates, or degenerative intervertebral discs (Ledet et al 2006).

Current treatments for back pain generally aim to alleviate the symptom rather than resolve the disease itself, as this is often difficult (Ledet et al 2006). Conservative treatments are utilised before surgery is considered. Conservative therapies may include reduced activity, analgesics, or rehabilitation programs. Upon failing conservative therapies, it is common for patients to undergo a spinal fusion procedure. Spinal fusion involves the surgical connection of two adjacent vertebrae to immobilise one or more motion segments in an attempt to relieve pain, correct deformity, and improve stability.

Indications for spinal fusion include evidence of preoperative segmental instability, stenosis with deformity that may result in progressive deformity after decompression, wide decompressions that may result in iatrogenic instability, and recurrent disc herniations in some patients (Shen et al 2007).

Spinal fusions have been performed for almost a century for a variety of conditions including infection, trauma, deformity, degenerative conditions, and after resection for spinal tumours (Shen et al 2007). The first lumbar interbody fusion (anterior approach) was reported in the 1930s (Shen et al 2007). This pioneer procedure was an open technique, as were many of the first spinal procedures. The introduction of new techniques and technologies and better understanding of surgical anatomy then gave rise to minimally invasive spine surgery (Shen et al 2007). In the 1950s a posterior approach to lumbar interbody fusion was described (Shen et al 2007). This procedure was designed to preserve facet joints and required nerve root retraction to allow for adequate root excision and placement of the interbody graft or cage (Shen et al 2007). Another procedure, transforaminal lumbar interbody fusion, was performed in an attempt to reduce the risk of nerve root injury seen when a posterior approach was employed. In the years that followed several other approaches to spinal fusions were developed including the extreme lateral/transpsoas approach (where access to the lumbar spine is achieved by a lateral approach that passes through the retroperitoneal fat and psoas major muscle) and more recently transaxial anterior lumbar interbody fusion (Shen et al 2007).

Transaxial anterior lumbar interbody fusion (AxiaLIF<sup>TM</sup>; TranS1® Inc., USA) involves an incision lateral to the coccyx and careful excision of the skin and underlying fascia (Shen et al 2007). The sacrum is separated from the rectum with a mesorectum covered by visceral fascia. This plane is easily penetrated and serves as the minimally invasive route to the sacrum. A guide pin introducer is advanced gently along the anterior midline of the sacrum (Shen et al 2007). Tactile feedback and fluoroscopic guidance is essential during the entire AxiaLIF process to avoid iatrogenic complications of the spine or surrounding organs (Shen et al 2007). Once a tunnel is achieved to the inferior endplate of L5 a threaded reamer is inserted and the bone collected is saved for autologous bone

grafting (Shen et al 2007). Discectomy is performed using specially designed cutting-loop devices and disc extractors, and then bone graft material is packed directly into the disc space (Shen et al 2007). Finally, a drill is used to penetrate the L5 vertebral body (to within 1cm of the superior endplate of L5) so that a titanium-threaded rod can be implanted. This is often held in place with percutaneous pedicle screws (Shen et al 2007).

AxiaLIF has been limited by the availability of appropriate techniques and implants (Shen et al 2007). Many spinal surgeons are less familiar with presacral anatomy than general or colorectal surgeons are; therefore, it is critical that the operating surgeon gain a thorough understanding before carrying out the procedure in order to reduce the risk of complications (Shen et al 2007). Another disadvantage of the AxiaLIF procedure is the surgeon's inability to visualise the discectomy directly, due to the minimally invasive nature of the procedure (Shen et al 2007). This restricts the surgeon's ability to address intracanal pathology (Shen et al 2007).

Particular benefits of the minimally invasive nature of AxiaLIF include reduced injury and disruption of the posterior musculature, ligaments, or elements because the L5/S1 disc space is accessed through the presacral space, and a small incision compared with open procedures (Shen et al 2007). Similarly, the abdominal cavity does not need to be entered and mobilisation or retraction of the vasculature or intra-abdominal viscera is not necessary (Shen et al 2007).

#### **CLINICAL NEED AND BURDEN OF DISEASE**

In 2001, back pain/disc disorders were the third most commonly reported long-term conditions causing pain and illness in Australia (Australian Institute of Health and Welfare 2010a). A total of 3,937,000 persons reported back pain/disc disorders as a long-term condition, which equates to 20.9% of all long-term conditions reported at that time. Of these sufferers, 1,944,000 were men (21% of all men with long-term conditions) and 1,993,000 were women (20.7% of all women with long-term conditions) (Australian Institute of Health and Welfare 2010a).

In another report issued by the Australian Institute of Health and Welfare in 2003, there were a total of 29,658 disability-adjusted life year calculated for all patients with back pain (chronic and acute) (Australian Institute of Health and Welfare 2003). Men accounted for 14,470 of these years and women for 15,188. Death with back pain as the main cause occurred in 26 people (16 men, 10 women) and prevalent years lived with a disability was 27,411 years (13,206 years in men, 14,205 years in women). The total number of years lost due to back pain in 2003 was 173 years, with 115 years lost in men and 59 years lost in women. The overall incidence of back pain (including long-term incidence) was 9,045,837, with a majority of female (5,205,483) sufferers compared with male (3,840,354). In general the age group affected the most by back pain was 25-64 years, for both sexes (Australian Institute of Health and Welfare 2010b).

#### **DIFFUSION**

The first three AxiaLIF procedures were carried out in Brazil in May 2003 (TranS1® Inc. 2010). Since this time over 8,000 AxiaLIF procedures have been performed (TranS1® Inc. 2010). The US Food and Drug Administration (FDA) approved the use of AxiaLIF on June 14<sup>th</sup> 2005 (FDA 2010). In September 2006 a global leader in synthetic bone graft technologies (ApaTech) signed an exclusive agreement with the manufacturer of AxiaLIF to distribute the system in the UK and Ireland (ApaTech Press Information 2006). No literature could be found regarding the time at which AxiaLIF received CE mark approval for its use throughout Europe. The AxiaLIF device does not appear to have Therapeutic Goods Administration approval.

### **COMPARATORS**

Comparators for the AxiaLIF procedure to treat lower back pain include other fusion procedures with alternate means of accessing the L5/S1 disc space, or non-operative treatment. Comparator fusion procedures include retroperitoneal anterior lumbar interbody fusion and trans-peritoneal interbody fusion (Shen et al 2007).

### **SAFETY AND EFFECTIVENESS ISSUES**

Two studies were eligible for inclusion in this summary. Both studies were case series reporting outcomes in patients undergoing the AxiaLIF procedure (Aryan et al 2008; Luther et al 2009).

#### *Study description*

The multicentre retrospective study by Aryan et al (2008) reported outcomes in 35 patients (15 men, 20 women) who underwent spinal surgery to treat back pain using percutaneous paracoccygeal axial fluoroscopically-guided interbody fusion (the AxiaLIF procedure) with cage, local bone autograft, and recombinant human bone morphogenic protein. Twenty-one patients underwent the AxiaLIF procedure followed by percutaneous L5/S1 pedicle screw-rod fixation, two patients underwent AxiaLIF followed by percutaneous L4/L5 extreme lateral interbody fusion and posterior instrumentation, ten patients had a stand alone procedure, and two patients had unfavourable anatomy precluding access to the L5/S1 disc space during open lumbar interbody fusion and subsequently underwent AxiaLIF as a part of a larger construct. Back pain was secondary to lumbar degenerative disc disease (n=26), degenerative lumbar scoliosis (n=6), or lytic spondylolisthesis (n=3). The mean age of the patient population was 54 years.

The patients were followed up daily whilst in hospital and on an out-patient basis at 6 weeks, 3 months, 6 months, 1 year, and 2 years postoperatively. Average follow-up was 17.5 months (range 10-29 months). Fusion was determined based on the lack of hardware failure, lack of motion on flexion and extension plain films, and the presence of bridging trabecular bone.

The single centre retrospective cohort study conducted by Luther et al (2009) reported outcomes in six patients who underwent the AxiaLIF procedure from 2007 to 2008. All patients had symptomatic chronic back pain and radiographic evidence of lumbar degenerative disc disease at L5/S1. Some patients had previous failed operative interventions (not including disectomy with interbody fusion at L5/S1). The mean age of

the two men and four women undergoing the procedure was 59.5 years (range 39-78). Mean follow-up was 15.4 months, with lumbosacral spine imaging performed at a mean 9.6 months follow-up. Bony fusion of the L5/S1 was determined by lumbar anterior/posterior and lateral imaging, including flexion/extension images.

### *Safety*

In the study by Aryan et al (2008) mean blood loss was 30mL (for the AxiaLIF portion of each procedure only). One patient suffered local infection at the incision site, which was successfully treated with oral antibiotics. There were no cases of bowel or rectal injury as a result of the procedure.

Luther et al (2009) reported good tolerance to the procedure in all patients, with normal neurological function seen postoperatively. Mean blood loss was 80mL (range, 50-200mL) with no significant vascular injury in any case.

### *Effectiveness*

Mean operative time for the L5/S1 AxiaLIF procedure in the study by Aryan et al (2008) was 42 minutes. For patients receiving this procedure alone, average hospital stay was 21 hours. Ninety-one percent (32/35) of patients had radiographic evidence of stable L5/S1 interbody cage placement and fusion at 12 month follow-up. Of the patients without evidence of fusion, two received AxiaLIF alone and one received AxiaLIF in conjunction with percutaneous L4/L5 extreme lateral interbody fusion and posterior instrumentation. One stand alone patient opted for supplemental posterior percutaneous fixation (one-year outcomes pending) and the other opted for continued observation. The third patient, who received AxiaLIF with percutaneous L4/L5 extreme lateral interbody fusion and posterior instrumentation, requested the AxiaLIF implant be removed. This was achieved through an anterior retroperitoneal approach where the anterior sacral was resected, the implant removed, the disc space prepared, and a bone graft placed for anterior fusion (at 6 months the patient was doing well and there was CT evidence of fusion). Specifically, fusion rate at one-year was 100% in patients who received AxiaLIF with pedicle screws, 80% in patients who received the stand alone procedure, 50% in patients who received AxiaLIF with extreme lateral interbody fusion and pedicle screws, and 100% in patients who received AxiaLIF as part of a large construct.

Average graft subsidence was 2mm in patients receiving AxiaLIF alone. Greater graft subsidence was not associated with poorer clinical outcomes. Preoperative Oswestry disability index (ODI)<sup>1</sup> score for all patients collectively was 42% and increased initially at 3 weeks postoperative to 48%, before steadily decreasing to 35%, 30%, 24%, and 22% at 6 weeks, 3 months, 6 months and 12 months postoperative, respectively. Similarly, pain measured on the visual analogue scale (VAS) decreased from 75 preoperatively to 50 at 3 weeks postoperative, 51 at 6 weeks, 40 at 3 months, 35 at 6 months, and 31 at 12 months.

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<sup>1</sup> Oswestry disability index measures of patient's permanent function disability, where 0-20% indicates minimal disability, 21-40% indicates moderate disability, 41-60% indicates severe disability, 61-80% indicates the patient is crippled, and 81-100% indicates bed-bound patients (Fairbank and Pynsent 2000).

In the study by Luther et al (2009) there were no technical errors observed; all implanted screws were placed in the correct position, and no misplacement or drift was seen by comparing intraoperative images with computer 3 dimensional navigation screenshots and postoperative imaging. There was no need for reoperation in any of the patients. Mean back/leg pain, measured on the VAS, reduced significantly postoperatively from 7.8 for back pain and 8.0 for leg pain to 2.8 for both back and leg pain (P<0.02). There was also a significant improvement in ODI score, from 56% to 26% postoperatively (P<0.05). Bony fusion was evident on postoperatively imaging in 17% (1/6) of patients at 12 months follow-up.

### **COST IMPACT**

The Australian Medicare Benefits Schedule (MBS) includes six item numbers for anterior interbody spinal fusion. These are listed below in Table 1 (MBS 2010).

Table 1: MBS descriptors for anterior interbody spinal fusion.

Item Number	Description	Cost
48660	SPINAL FUSION (anterior interbody) to cervical, thoracic or lumbar regions - 1 level, not being a service associated with artificial intervertebral total disc replacement	Fee: \$1,023.25 Benefit: 75% = \$767.45
48663	SPINAL FUSION (anterior interbody) to cervical, thoracic or lumbar regions - 1 level (where an assisting surgeon performs the approach) - principal surgeon	Fee: \$765.10 Benefit: 75% = \$573.85
48666	SPINAL FUSION (anterior interbody) to cervical, thoracic or lumbar regions - 1 level (where an assisting surgeon performs the approach) - assisting surgeon	Fee: \$462.65 Benefit: 75% = \$347.00
48669	SPINAL FUSION (anterior interbody) to cervical, thoracic or lumbar regions - more than 1 level, not being a service associated with artificial intervertebral total disc replacement	Fee: \$1,379.10 Benefit: 75% = \$1,034.35
48672	SPINAL FUSION (anterior interbody) to cervical, thoracic or lumbar regions - more than 1 level (where an assisting surgeon performs the approach) - principal surgeon	Fee: \$1,032.30 Benefit: 75% = \$774.25
48675	SPINAL FUSION (anterior interbody) to cervical, thoracic or lumbar regions - more than 1 level (where an assisting surgeon performs the approach) - assisting surgeon	Fee: \$622.95 Benefit: 75% = \$467.25

There were no peer-reviewed cost-effectiveness studies identified from the literature; however, AxiaLIF appears to offer a more cost effective alternative to standard fusion techniques due to improved patient outcomes (TranS1® Inc. 2010). These outcomes include reduced rate of reoperation, and more rapid pain relief (TranS1® Inc. 2010).

### **ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

There were no issues identified from the retrieved material.

## **OTHER ISSUES**

There were no issues identified from the retrieved material.

## **SUMMARY OF FINDINGS**

Based on the findings of the two included case series, the AxiaLIF procedure appears to be relatively safe with no major complications encountered and minimal blood loss experienced. Effectiveness in terms of the primary outcome of the procedure (spinal fusion) varied between the two studies. At 12 months follow-up one study reported a high level of procedural success (91% fusion rate), and the other reported fusion in only 17% of patients. The number of patients in the second study was considerably smaller and preoperative ODI was higher, compared with the first study. Success in regards to pain and disability improvement was apparent in both studies, with significant improvements seen for both outcomes. Overall, the AxiaLIF procedure appears to offer some symptom improvement in patients suffering from back pain, without major compromise to their safety. High-quality comparative studies are needed to completely assess the safety and efficacy of the AxiaLIF procedure.

## **HEALTHPACT ACTION**

Due to the lack of high quality evidence at the time of writing and the need for long-term studies, AxiaLIF has been noted by HealthPACT and further assessment at this point of time by HealthPACT is not necessary.

## **NUMBER OF STUDIES INCLUDED**

Total number of studies	2
Level IV evidence	2

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#### **SEARCH CRITERIA TO BE USED**

Axialif, Axial lumbar interbody fusion