National Institute for Health and Care Excellence

IP744/2 - Lateral interbody fusion in the lumbar spine for low back pain
Consultation Comments Table

IPAC date: 8 December 2016

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Society of British Neurological Surgeons (SBNS).	1	It is a safe approach that should be part of procedures performed in a specialised spinal surgery department.	Thank you for your comment. Section 1.2 of the guidance states 'This procedure should only be done by surgeons with specific training in the technique, who should carry out their initial procedures with an experienced mentor.'
2	Consultee 2 Company Zimmer Biomet	1	Zimmer Biomet welcomes the updated guidance. The updated consultation guidance reflects current evidence, supporting efficacy of the procedures concerned.	Thank you for your comment.

3	Consultee 2 Company Zimmer Biomet	1	Section 1.1 states “Current evidence on the safety of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine for low back pain shows there are serious but well-recognised complications.” NICE should also consider including a statement comparing the rate of complications observed in these procedures, with those of ALIF, TLIF and MI-LIF. The literature reviewed suggests that there is not an additional risk, either in nature or in rate expected, particularly if neuromonitoring were standard.	Thank you for your comment. The IP programme does not assess the efficacy and safety of comparator interventions. The rate of complications reported in comparative studies are included in section 5 of the guidance.
4	Consultee 2 Company Zimmer Biomet	1	In addition to the draft recommendations shown, NICE should also consider including a statement in the recommendations which encourages neuromonitoring as standard practice in the avoidance of complications. The safety evidence reviewed in Study 2 Híradó (2016) , Study 4 Smith WD (2012) and Study 6 Hrabalek L (2014), together with the statements made in 3.2, 5.1 , 5.4 and 6.2 regarding neuromonitoring and adverse events, indicate that this should be routine, standard practice , with the possible exception of where the surgical approach avoids the psoas muscle entirely.	Thank you for your comment. The guidance has a Committee Comment, stating that ‘nerve monitoring is increasingly being used with the intention of reducing neurological injury.’

5	Consultee 1 Society of British Neurological Surgeons (SBNS).	2	The procedure is performed to relieve low back pain with or without sciatica. The procedure is able to achieve decompression of the affected nerve root. It can also be used as a part of correction surgery for Degenerative Scoliosis.	Thank you for your comment. A committee comment has been added to the guidance, noting that the procedure is also used to treat back pain with sciatica, and scoliosis. Scoliosis was not considered to be within the remit of this guidance. Studies that only included patients with scoliosis were excluded where possible, although some were included in the systematic reviews. This is noted in the overview.
6	Consultee 1 Society of British Neurological Surgeons (SBNS).	2	The correction of lordosis and scoliosis is better.	Thank you for your comment. A committee comment has been added to the guidance, noting that the procedure is also used to treat back pain with sciatica, and scoliosis. Scoliosis was not considered to be within the remit of this guidance. Studies that only included patients with scoliosis were excluded where possible, although some were included in the systematic reviews. This is noted in the overview.
7	Consultee 1 Society of British Neurological Surgeons (SBNS).	3	The advantages include minimal muscle dissection and wound complications.	Thank you for your comment. Section 3 of the guidance states that the procedure aims to avoid the major muscle groups in the back (posterior approach) and the organs and blood vessels in the abdomen (anterior approach).

8	Consultee 2 Company Zimmer Biomet	4	Efficacy. Patient satisfaction for the procedure is high and this could be included in the document in section 4, or elsewhere. Study 7: Khajavi: 93% “Patient satisfaction for the entire group was 93 % when asked whether satisfied with surgical outcome.” In other clinical papers reviewed, at least 80% of treated patients indicated that they would have the procedure again if their outcome had been known in advance.	Thank you for your comment. Section 4.4 of the guidance includes data on patient satisfaction: ‘In the systematic review of 237 articles, the weighted average for patient satisfaction was 89% (n=491 patients, 9 study arms); 85% of patients said that they would have the procedure again if their outcome had been known in advance. In a randomised controlled trial (RCT) and non-randomised comparative study of 55 patients treated by XLIF or transforaminal interbody fusion (TLIF), 91% and 80% of patients respectively were satisfied with their outcome at 24-month follow-up (p=0.393) and 100% and 90% of patients respectively would be willing to have the same procedure had their outcome been known in advance (p=0.210). In a non-randomised comparative study of 208 patients treated by XLIF or ALIF, 95% (198/208) of patients were satisfied with the procedure and reported improvement; 10 patients did not improve or worsened (radiological and clinical results were similar in both groups).’ The following outcome from the Khajavi study will be added to the overview: ‘Patient satisfaction for the entire group was 93% when asked whether satisfied with surgical outcome; 93% of patients indicated they would do the surgery again, given their current outcome.’

9	Consultee 1 Society of British Neurological Surgeons (SBNS).	5	It is a relatively safe procedure provided adequate precautions are taken including intra-operative spinal nerve monitoring (especially at the L3/4 and L4/5 levels).	Thank you for your comment. Section 6 of the guidance states that 'Nerve monitoring is increasingly being used with the intention of reducing neurological injury.'
10	Consultee 1 Society of British Neurological Surgeons (SBNS).	5	The risk of temporary neurological complications is higher than anterior or posterior methods but most patients improve within 3 months.	Thank you for your comment. Safety data from published peer-reviewed studies have been included in section 5 of the guidance.
11	Consultee 2 Company Zimmer Biomet	5	Safety. NICE should consider including an additional statement on the relative intra-operative blood loss for Lateral Fusion procedures compared with other techniques. The main purpose of the lateral approach is to avoid vascular and neurological injury and in the evidence considered, there are clear advantages in reducing blood loss this respect shown in Study 2 Híradó (2016), Study 4 Smith WD (2012), Study 5 Isaacs RE and Sembrano JN (2016), Study 7 Khajavi K (2015) and in several other papers in Appendix A	Thank you for your comment. The guidance is intended to capture only the key safety and efficacy points. Further details of other outcomes, including estimated blood loss, are included in the overview (NB Study 2 in the overview is Härtl R et al., 2016 and not Hirado, 2016 as cited by the consultee). The IP programme does not assess the efficacy and safety of comparator interventions.

12	Consultee 1 Society of British Neurological Surgeons (SBNS).	General	The following are the comments from the Society of British Neurological Surgeons (SBNS). These comments are independent of the comments from BASS. Please note that Neurosurgeons deliver the major component of spinal surgery in England.	Thank you for your comment.
13	Consultee 2 Company Zimmer Biomet	General	Zimmer Biomet has not identified any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination and promote equality and foster good relations between people with a characteristic protected by the equalities legislation and others.	Thank you for your comment.