The role of spinal surgery in the treatment of low back pain

Lachlan Evans[1], Thomas O'Donohoe[1], Andrew Morokoff[1,2], Katharine Drummond[1,2]

Summary

- Low back pain (LBP) is common and a leading cause of disability and lost productivity worldwide.
- Acute LBP is frequently self-resolving, but recurrence is common, and a significant proportion of patients will develop chronic pain. This transition is perpetuated by anatomical, biological, psychological and social factors.
- Chronic LBP should be managed with a holistic biopsychosocial approach of generally non-surgical measures.
- Spinal surgery has a role in alleviating radicular pain and disability resulting from neural compression, or where back pain relates to cancer, infection, or gross instability.
- Spinal surgery for all other forms of back pain is unsupported by clinical data, and the broader evidence base for spinal surgery in the management of LBP is poor and suggests it is ineffective. Emerging areas of interest include selection of a minority of patients who may benefit from surgery based on spinal sagittal alignment and/or nuclear medicine scans, but an evidence base is absent.
- Spinal surgery for back pain has increased substantially over recent decades, and disproportionately among privately insured patients, thus the contribution of industry and third-party payers to this increase, and their involvement in published research, requires careful consideration.

Low back pain (LBP) is common, increasingly prevalent[1] and the leading cause of lost productivity worldwide.[2] Most LBP is generated by non-specific degenerative changes affecting the bone and soft tissue of the spine, with congenital and acquired deformity, infection, malignancy and trauma comprising a much smaller cohort.[3] It is estimated to account for $4.8 billion in lost annual individual earnings, $622 million in additional welfare repayments and $2.9 billion in lost gross domestic product in Australia alone.[4] Acute LBP resolves in many patients,[5] but recurrence is common and about 60% will develop chronic pain.[6] This transition is perpetuated by a complex interaction of anatomical, biological, psychological and social factors and, as with other forms of chronic pain, is best addressed with an integrated, comprehensive and multidisciplinary pain management program rather than fragmented care.[7-9] A significant proportion of patients with chronic LBP seek care from their general practitioner and, contrary to the recommendation of several guidelines,[10-12] a little over half of patients in high income countries undergo spinal imaging.[13,14] Given the high rates of imaging abnormalities of degenerative spinal disease in both symptomatic and asymptomatic individuals (34.4% of asymptomatic patients in one meta-analysis),[15,16] the findings frequently prompt referral to a spinal surgeon. This may then be associated with increased rates of intervention, resource utilisation, and the potential for adverse outcomes.[17] Surgical intervention for LBP is continuing to increase in Australia and disproportionately in privately insured patients.[18-20] Although spinal surgery has a role in the management of back pain related to significant instability, particularly in the context of cancer, infection or previous surgery, its role in the management of non-specific LBP remains without an evidence base. The objective of this review was to evaluate the current evidence base for spinal surgery in the treatment of axial LBP and highlight important factors that may influence practice.

Methods and definitions

This narrative review focused on studies of any design involving adult patients (aged ≥ 18 years) with axial pain affecting the region of the lumbar spine. We acknowledge the myriad aetiologies of axial LBP and the corollary that treatment strategies must address the underlying cause and, as such, are similarly diverse. The focus of this review is on patients experiencing axial LBP secondary to non-specific degenerative changes such as facet arthropathy, disc degeneration and soft tissue abnormalities. Studies on neurogenic claudication or radiculopathy treated with surgery were excluded as were those evaluating patients with significant structural abnormalities such as spondylolisthesis and fractures. Studies reporting spinal cord stimulation, radiofrequency ablation or percutaneous administration of epidural analgesia were also considered beyond the scope of our discussion. We performed an electronic search of the MEDLINE database for articles published from 1 January 1991 to 31 December 2021, without restriction of language. We employed the following search strategy: "lower back pain OR lumbar back pain" AND "surg* OR operati*". Articles were not excluded based on study design. The study quality was assessed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria.[21]

The role of spinal surgery for patients with neural compression

Decompressive spine surgery is widely accepted (but with a low evidence base) for the management of conditions associated with neural compression, including refractory radicular leg pain secondary to lumbar disc herniation,[22,23] and neurogenic claudication due to spinal canal stenosis.[24] Both conditions are relatively common in clinical practice, with an estimated 10% lifetime incidence of symptomatic lumbar canal stenosis and an annual incidence of lumbar radiculopathy in one American study of 4.96 cases per 1000 patient years.[25,26] The goal of this surgery is neural decompression with alleviation of neurogenic pain or deficits and improvement of functional mobility; however, it has been associated with an improvement in axial low back pain as measured by the Visual Analogue Scale (VAS) in almost two-thirds of patients in uncontrolled studies.[27] Similarly, decompression and stabilisation surgery has been demonstrated to improve pain, function and quality of life among selected patients with spinal metastases, particularly for neural decompression to avoid disability.[28-30] This has prompted the development of a number of scoring tools aimed at predicting

[1] Royal Melbourne Hospital, Melbourne, VIC. [2] University of Melbourne, Melbourne, VIC. kate.drummond@mh.org.au • doi: 10.5694/mja2.51788

those who will benefit from surgery in this context,[31,32] and forms the basis of the recommendation for neuroimaging among patients with LBP and red flag symptoms in a number of guidelines (Box 1).[10-12]

The role of spinal surgery in degenerative low back pain

The evidence supporting spinal surgery for the treatment of LBP in the absence of neural compression, infection, cancer, or gross instability is sparse and contrasts with the increasing frequency at which this surgery is being performed.[20] Existing literature can be dichotomised into trials comparing surgical intervention (decompression, fusion or other) against non-operative management and those comparing different surgical strategies or techniques. Previous analyses have denoted these two categories as "indication" and "technique" trials respectively.[33] The majority of studies fall into the latter group, are of poor quality, and generally aim for a non-inferiority analysis of complications and outcomes of a specific technique, rather than efficacy in the management of LBP.[33-35] There is often significant investment of industry and device manufacturers in such trials, which is well recognised to bias results.[36,37] The analysis of these studies does not inform the question of the indication for spinal surgery for LBP and may be misleading, as it assumes the efficacy of both procedures.

We identified five randomised controlled trials (RCTs) comparing spinal surgery and non-operative measures for the treatment of degenerative LBP (Box 2). All were published between 2001 and 2011. Of the five studies, two reported statistically significant improvements in LBP with surgical intervention. An RCT from the Swedish Lumbar Spine Study Group found that lumbar fusion improved LBP (quantified by VAS) and three measures of disability (Oswestry Disability Index [ODI], Million Score, and General Function Score) in comparison to standard conservative management (n = 294).[42] The immediate postoperative complication rate was 17%. Furthermore, a Japanese trial also showed a statistically significant improvement in LBP with lumbar fusion (n = 40).[38] However, neither of these studies referenced the minimal clinically important difference (MCID) — a measure describing the threshold change in an outcome that is clinically, rather than just statistically, significant for patients.[43,44] The remaining three RCTs found no benefit of spinal surgery for LBP. A trial published in 2005 described a small, statistically significant, improvement with lumbar fusion that did not meet the threshold of MCID (n = 349).[40] The other two RCTs reported on a cohort of Norwegian patients with degenerative LBP (n = 64) and subsequently on an additional group of patients who had undergone previous lumbar microdiscectomy with persistent axial LBP (n = 60).[39,41] Neither trial found a statistically or clinically significant benefit with lumbar fusion.

Despite adequate randomisation, the above trials are at substantial risk of bias given the lack of patient, surgeon and assessor blinding. Additionally, previous well designed studies have shown the placebo effect of surgical interventions to be significant, and given the propensity for LBP to wax and wane, very long term follow-up is necessary.[45] Using the GRADE system, a standardised criterion against which the quality and risk of bias in an individual study can be evaluated, all five RCTs consist of low to moderate levels of evidence (Box 3).[21]

These findings have been synthesised in numerous systematic reviews and augmented by long term follow-up data from the three major RCTs examining cohorts from the United Kingdom, Norway and Sweden.[46-48] A systematic review included studies evaluating the treatment of LBP only and pooled data from the above five RCTs (n = 707), comparing patients undergoing lumbar fusion (n = 523) with those managed conservatively (n = 134).[49] After a meta-analysis, a non-significant reduction in the ODI of -7.39 points was reported (95% CI, -20.26 to 5.47; P = 0.26).[49] Postoperative complications were identified in 9–18% of patients undergoing lumbar fusion.[49] Several reviews have broadly examined the role of spinal surgery in degenerative lumbar spine disease, including LBP, radiculopathy and spinal stenosis.[48,50,51] One such review provided the basis for the 2009 American Pain Society guidelines on the use of spinal surgery in degenerative lumbar spine disease.[50] Consistent with the individual studies described above, the authors found that lumbar fusion was no better than intensive rehabilitation and cognitive behavioural therapy for the treatment of LBP. However, based on data published in 2001,[42] they concluded that lumbar fusion is slightly superior to standard, non-intensive conservative management. Of note, the authors of the study found that less than half of patients reported an optimal outcome (no more than sporadic pain, slight functional restriction, or occasional analgesic use) after lumbar fusion.[50]

Limitations of the spinal surgery literature

A key factor limiting the comparison between trials is the significant difference between the type and intensity of non-operative management. In trials reporting comparable results between the two groups, non-operative patients underwent intensive physical rehabilitation as well as cognitive behavioural therapy.[39-41] In comparison, the conservative arms of two studies undertook standard, non-intensive treatment.[38,42] The risk of negative motivation bias in these latter two studies is substantial. Most of the participants had been undertaking standard physiotherapy and pain management for many years and, when assigned to the study arm continuing this previously ineffective treatment (which occurred in a 1:3 ratio compared with the fusion arm), the perception of a poor outcome is likely to be amplified. As such, the benefit of surgical intervention will be exaggerated. However, specialised physical and psychological therapy provided to patients in the British and Norwegian trials may not be available in all health care settings.

Long term follow-up data have reinforced the initial findings from the British and Norwegian cohorts as well as several meta-analyses combining the five available RCTs. After an average follow-up of 11 years, combined data from three studies[39-41] demonstrated no difference in outcome between patients

1 Red flag symptoms that should raise suspicion for significant pathology in patients presenting with axial low back pain[3]

Symptom	Possible aetiology
History of cancer	Metastatic spread of malignancy to the spine
Unexplained weight loss	Metastatic malignancy or chronic infection
Fever, night sweats and/or rigors	Spinal infection such as osteomyelitis, discitis, or epidural abscess
Trauma	Fractures
Neurological deficit	Any pathology resulting in compression of the spinal cord or nerve roots
Age < 40 years	Congenital deformity such as spondylolisthesis or scoliosis, infection and fractures

2 Randomised controlled trials of surgery versus non-operative treatment for low back pain

Study (year)	Number of patients	Follow-up (months)	Intervention	Result	GRADE*
Ohtori[38] (2011)	41	24	Fusion *v* minimal treatment	VAS, JOAS, ODI significantly improved with surgery ($P < 0.05$)	Low
Brox[39] (2006)	60	12	Fusion *v* cognitive + exercises	ODI no significant difference ($P = 0.15$)	Moderate
Fairbank[40] (2005)	349	24	Fusion *v* intensive rehabilitation	ODI reduced 4.1 in favour of surgery ($P = 0.045$)	Moderate
Brox[41] (2003)	64	12	Fusion *v* cognitive + exercises	ODI reduced 2.3 ($P = 0.33$)	Moderate
Fritzell[42] (2003)	294	24	Fusion *v* physical therapy	VAS reduced in surgical group 33% *v* 7%; ODI 25% *v* 6%	Moderate

GRADE = Grading of Recommendations Assessment, Development and Evaluation; JOAS = Japanese Orthopaedic Association Score; ODI = Oswestry Disability Index; VAS = Visual Analogue Scale. * Low: the true effect might be markedly different from the estimated effect. Moderate: the authors believe that the true effect is probably close to the estimated effect. ◆

managed conservatively versus those managed with lumbar fusion.[47] Conversely, long term data from the Swedish study reported a statistically significant improvement in the Global Assessment metric for patients undergoing lumbar fusion when analysed on a per protocol basis.[46] That is, only data from patients who completed the treatment to which they were initially randomly allocated were included. The risk of bias using this type of analysis is well recognised.[52,53] Based on this single outcome, the authors concluded that lumbar fusion is a viable treatment option for LBP. However, this assertion has attracted robust criticism.[54] The authors provided long term data on several other outcome measures, including the ODI, visual analogue pain scale, work status and ongoing analgesic requirement, all of which demonstrated no difference between the two study groups.[46] In addition, when analysed on an intention-to-treat basis there was no difference in the Global Assessment score between conservative and surgical management.[46] As such, clinicians should interpret the results of this latter study with caution. The difficulties with obtaining accurate, objective and reproducible outcome data for patients with chronic pain are highlighted by the controversial long term results reported by the Swedish group.

The small number of aforementioned studies are fundamental to understanding if spinal surgery (in any form) is superior to best conservative management for the treatment of degenerative LBP. Despite their importance, they comprise only a minority of the literature on this topic.[33] Instead, the literature is dominated by small, industry-supported RCTs that compare one specific surgical technique with another, with the implicit assumption that both are superior to non-operative management. Describing this body of literature is beyond the scope of this review. However, it must again be emphasised that their objective is not to substantiate the benefit of surgery. Rather, they aim to compare surgical nuances and thus have no value to guide the appropriateness of specialist referral or spinal surgery for patients with LBP, but the effect of the assumption that surgery is effective implicit in such literature is likely to be substantial. Analysing the relevant literature from 1993 to 2012, a 2013 study reported that 33 of 39 identified RCTs assessed technique rather than indication, which was assumed.[33] Furthermore, this article underscored the bias introduced by selective citation of previous positive trials. Evaluating the number of citations of the three key RCTs over a 24-month period in 2010–2011, they found that surgeon authors disproportionately referenced the Swedish study[42] that supported the use of spinal surgery (134 citations).[33] In comparison, the two negative trials[39,40] received far fewer citations (54 and 51 respectively).[33] There was no significant difference in citation frequency by non-surgeon authors.

There is a clear lack of evidence supporting the use of spinal surgery for the treatment of LBP. Importantly, the currently available studies up to 2011 do not address much that has changed over the past 10 years in spinal surgery. Minimally invasive fusion techniques, improved implant materials, and a better understanding of sagittal alignment have yet to be rigorously tested in high quality randomised trials and, hence, their impact on the efficacy of spinal surgery remains unknown. The difficulties with successfully conducting unbiased randomised trials of spinal surgery have been detailed above. Transparent multicentre trials independent from industry are fundamental to more adequately establish the benefit of modern surgical techniques and move beyond this impasse. Consistent with previous trials in the spinal[55] and non-spinal[56-58] literature, these trials should be independent from industry and be supported

3 Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria analysis of the five key randomised trials

Study (year)	Risk of bias*	Inconsistency	Indirectness	Imprecision	Publication bias	Quality*
Ohtori[38] (2011)	Moderate	None	None	Minor	None	Low
Brox[39] (2006)	Minor	None	None	None	None	Moderate
Fairbank[40] (2005)	Minor	None	None	None	None	Moderate
Brox[41] (2003)	Minor	None	None	None	None	Moderate
Fritzell[42] (2003)	Minor	None	None	None	None	Moderate

* Low: the true effect might be markedly different from the estimated effect. Moderate: the authors believe that the true effect is probably close to the estimated effect. ◆

by philanthropic and governmental research funding agencies. In a similar vein, the methodological flaws and systemic biases present within the existing literature must be acknowledged.

Emerging areas of interest

The substantial heterogeneity in the biological, psychological and social circumstances of patients with LBP may have contributed to the failure of previous trials. Thus, there may be unidentified subgroups of patients with LBP who would benefit from surgery. This would rely on identification of reliable investigations to identify surgical candidates. There is some evidence for the use of lumbar discography to identify discs generating pain, but this technique remains controversial and is invasive.[59] There has also been significant interest in the role of single-photon emission computed tomography (SPECT) with computed tomography (CT) to assess inflammation of discs and facet joints that could be pain generators.[60] However, as for magnetic resonance imaging evidence of degenerative disease, SPECT-CT abnormalities are common in healthy pain-free controls,[60] and a Korean study observed no significant difference between patients receiving targeted pain interventions who did (n = 110, 73.83%) and did not (n = 17, 65.38%) have changes on SPECT-CT (P = 0.37).[61] Over the past three decades, there has also been growing interest in the relationship between the sagittal alignment of the spine and LBP.[62,63] This has prompted some surgeons to routinely obtain standing lateral and antero-posterior x-rays to measure sagittal alignment. However, there is significant variability in spinal and pelvic alignment in healthy controls,[64,65] which creates difficulty in specifically defining pathological sagittal imbalance. Moreover, although it has garnered increasing support as an outcome measure among patients undergoing deformity correction procedures,[66] changes in sagittal alignment are commonly observed with age,[67] and the role of surgical restoration of physiological parameters for the treatment of LBP remains investigative. For these reasons, routine imaging of patients with LBP with SPECT-CT or standing x-rays is not recommended in any of the major international LBP guidelines.[10-12] These imaging modalities may be appropriate adjunctive investigations among patients in whom a decision has already been made to operate.

Lumbar disc arthroplasty, in which a diseased intervertebral disc is removed entirely and replaced with an artificial disc, has been expounded as a motion-preserving treatment for discogenic LBP.[68] However, no high quality RCTs have found a clinically significant benefit in comparison to lumbar fusion or non-operative management.[69-71] Again, the literature is thus far dominated by technique trials assessing different types of artificial discs as well as small non-inferiority studies comparing arthroplasty with lumbar fusion.[70,72]

Finally, in light of the increased incidence of LBP in obese patients,[73] there has been increasing attention and reports of LBP improvement in patients achieving weight loss after bariatric surgery.[74,75] However, these data are derived from a small number of uncontrolled studies, and whether bariatric surgery is superior to a holistic program of non-operative interventions for the treatment of LBP among obese patients remains conjectural.

Industry influence

Given the increasing frequency and complexity of spinal surgery,[20] it is essential to consider the cost to the health care system, with spinal fusions being recently estimated to cost \$46 288 ± \$22 112 per episode in Australia.[76] It is also essential to consider the role of industry and device manufacturers. The exponential growth of spinal fusion, particularly in the private sector, has driven (and is likely been driven by) a concomitant increase in the development of new implants and instrumentation techniques.[20,76] The detrimental association between industry and research is well documented across the medical literature and may, in part, explain the predominance of technique trials detailed previously.[77] A 2017 analysis of nearly 6000 North American spine surgeons found that 91.6% reported at least one financial relationship with industry.[78] Such associations are common across modern health care, but the central role of implants and instrumentation in many contemporary spinal operations heightens the risk of industry influence.[79] Furthermore, while financial association alone does not prove that an individual surgeon's practice has been unduly altered, the impact of financial support on guideline formation, clinical decision making, and prescribing is well documented in other areas of medicine.[80-82] A review of articles published from 2002 to 2003 found that 15.9% reported industry funding (57.9% of articles did not disclose a funding source).[83] The same study noted industry-funded trials were 3.3 times more likely to report a positive outcome compared with other trials ($P < 0.001$).[83] Despite the above, surgeons consistently state that they do not consider this relationship a significant determinant of their practice.[84] The authors recognise the many benefits that transparent cooperation between clinicians and industry can have in supporting research and development as well as financing large-scale, randomised trials that would otherwise be difficult to complete in the public health care system. However, given the rapid and lucrative expansion of instrumented spinal fusion for both LBP and neural decompression, the influence of this interplay on research quality and ethics, public health policy, and individual patient outcomes warrant careful consideration. The use of spinal surgery for the treatment of LBP is an important example of the complex intersection between a poor evidence base, industry involvement, and a demanding patient population.

Conclusion

The increasing burden of LBP presents a significant challenge to health care systems throughout the world. Its management should be overseen by primary care physicians and centred upon a holistic biopsychosocial approach of generally non-surgical interventions. Even though spinal surgery does have a role in alleviating symptoms of radiculopathy or neurogenic claudication, or in circumstances where back pain is related to cancer, infection or gross instability, its role in the management of degenerative LBP is not supported by the studies currently available. Despite this, surgical intervention for LBP has increased substantially among Australian patients, and disproportionately among those with private health insurance. The contribution of industry toward this increase, and their role in the conduct of published research, requires further scrutiny.

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