MINI-SYMPOSIUM: FRONTIERS IN SPINE SURGERY

(ii) The role of surgery in low back pain

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Back pain; Lumbar disc degeneration; Discography; Spinal fusion; Artificial disc replacement; Magnetic resonance imaging

Summary
Spinal fusion for low back pain (LBP) in the absence of serious underlying disease is controversial. The cause of serious LBP illness is not well understood, there is poor correlation of the presence and degree of degenerative changes with symptoms and non-structural factors such as central pain intolerance, psychological distress, social and economic issues of compensation and participation, appear to act as co-morbidities to LBP illness. Fusion surgery appears to offer only limited relative benefits over cognitive behavioural therapy and intensive rehabilitation in RCTs of surgical vs. non-operative care. At best, possibly 50% of fusion patients in this setting have high-quality outcomes. Artificial disc replacement has approximately the same outcomes as fusion in short-term studies but the long-term risks of prosthesis placement in relatively young patients is a concern. Future surgical advances may be limited by a lack of clear diagnostic certainty and the high prevalence of serious co-morbidities that impair recovery.

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Introduction
Low back pain is common. Most episodes of LBP resolve without medical intervention; acute back pain will usually resolve in short order, but recurrent episodes are very common and persistent low-grade symptoms can be found years after the first episodes. The point prevalence and one-year prevalence of LBP may be as high as 33%,1 and 73%,2 respectively. In physically active adults such as manual labourers or soldiers undergoing physical training, the experience of LBP may be still higher or nearly universal.3 However, most people with persistent LBP do not report serious or persistent disability. While more than 70% of adults in a large population study reported back pain, only 10% had more than minimal functional problems.4 Even in persons with co-morbidities for development of disability, only less than 10% experienced any work loss greater than one week over a five years prospective observation.5

Surgical strategies for low back pain must be considered in the context of the presumed cause and course of the LBP syndrome being treated. The more specific and definitive the pathology, the easier the decision-making and the more predictable the outcome. For example, a patient with persistent LBP may have a relatively straightforward medical history and clear imaging pathology or, at the other extreme, no clear pathologic findings and a complex, chaotic emotional and social situation precluding reliable assessment.

In this context, for the surgeon evaluating a patient with back pain the issue is not why someone might have backache, because backache of varying intensities is so common. Rather the real question is why common backache

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is such a serious problem for this particular person. The answer may be simple when investigation demonstrates a destructive process such as myeloma, discitis or clear deformity and instability. However, more commonly the cause of the apparently severe LBP illness is obscure.

**Persistent LBP and lumbar spine degeneration**

While serious structural diseases of the spine may require complex and invasive treatment strategies, the overwhelming majority of persons with LBP will have non-specific findings rather than serious pathology on imaging studies. In clinical studies of patients with established LBP syndromes structural findings of disc degeneration, annular disruption and endplate changes are often seen. However, it is impossible to draw conclusions regarding the relationship of these findings to the complaint. In cross-sectional studies of subjects asymptomatic for serious LBP problems, MRI findings of disc degeneration, annular fissures and facet arthrosis have been commonly reported. It is impossible to draw conclusions regarding the relationship of these findings to the complaint. In cross-sectional studies of subjects asymptomatic for serious LBP problems, MRI findings of disc degeneration, annular fissures and facet arthrosis have been commonly reported. However, it is impossible to draw conclusions regarding the relationship of these findings to the complaint. In cross-sectional studies of subjects asymptomatic for serious LBP problems, MRI findings of disc degeneration, annular fissures and facet arthrosis have been commonly reported. However, it is impossible to draw conclusions regarding the relationship of these findings to the complaint. In cross-sectional studies of subjects asymptomatic for serious LBP problems, MRI findings of disc degeneration, annular fissures and facet arthrosis have been commonly reported. However, it is impossible to draw conclusions regarding the relationship of these findings to the complaint. In cross-sectional studies of subjects asymptomatic for serious LBP problems, MRI findings of disc degeneration, annular fissures and facet arthrosis have been commonly reported. However, it is impossible to draw conclusions regarding the relationship of these findings to the complaint. In cross-sectional studies of subjects asymptomatic for serious LBP problems, MRI findings of disc degeneration, annular fissures and facet arthrosis have been commonly reported. However, it is impossible to draw conclusions regarding the relationship of these findings to the complaint. In cross-sectional studies of subjects asymptomatic for serious LBP problems, MRI findings of disc degeneration, annular fissures and facet arthrosis have been commonly reported.

Prospective studies of MRI in subjects without serious LBP problems at baseline found that the subsequent development of LBP problems correlated poorly or not at all with baseline MRI findings. Rather future LBP troubles were most strongly predicted by psychological factors, social or occupational factors, or other chronic pain processes. Furthermore, in studies in which MR images are taken at baseline and repeated after 3 or more years, the new MRI findings developing over time were not well correlated with the development of new symptom-type or severity. In a different study design, subjects with known baseline degenerative changes during a stable and prolonged asymptomatic period, have been re-imaged soon after serious LBP episodes. This study design shows that new significant findings were very uncommon (<5%), suggesting that even serious LBP episodes are not due to any gross structural change in vast majority of cases. In fact, when a patient develops a serious disabling LBP episode, the likelihood of finding a de novo development of any of the lumbar findings commonly assumed to be associated with a “disc injury” is small, generally less than 20\% (Fig. 2).

**Special testing**

Because physical examination and even detailed imaging techniques have not found spinal pathology specific to those patients with serious LBP illness, attempts have been made to identify a hypothetical primary-symptomatic structure (“pain generator”) using provocative injections and anaesthetic blockade. The validity of these tests is not known as there is no histopathologic ‘gold standard’ against which a positive result could be tested. The issues of regional or central hyperalgesia, placebo or idiosyncratic responses are clearly important but not well quantified. Thus the results of these special diagnostic tests should be carefully considered in their clinical context. This is particularly true of provocative discography which is used to direct most types of invasive treatments (percutaneous disc interventions, fusion and disc arthroplasty). This tests the response of a patient when dye is injected into an intervertebral disc. If an injected, disrupted disc is painful and the pain is similar or exactly like a patient’s usual LBP, proponents have suggested that this result has definitively identified the cause of a patient’s pain. However, it has been shown that disc injection can simulate a quality and location of pain known not to originate from that disc (e.g. pelvic pain, bone tumour). Furthermore, disc injections are frequently painful (30–80%) in certain asymptomatic subjects, especially in the presence of psychological distress, previous disc surgery, remote chronic pain processes, or disputed compensation (Fig. 3). As most patients with chronic LBP illness have one or more of these co-morbidities, the risk of false positive results may be high in those individuals.

Even in subjects without co-morbidities a positive “best-case” discography injection (low pressure, annular disruption, negative adjacent discs, and normal psychosocial dimensions) results may still not accurately demonstrate which subject will have a high quality outcome from removing the supposed “pain generator”. A study was performed to evaluate diagnostic validity of discography in this best-case situation. Despite these “ideal” subjects achieving a solid fusion after anterior discectomy, less than half of these subjects had high-grade relief of symptoms.

**Figure 1** Prevalence of common changes on lumbar MR in adult subjects without serious LBP illness.
The positive predictive value of a single level positive injection in this best-case group appeared to be 50–60% for resolution of LBP illness after removal of suspected pain generator. Similarly, facet injections or sacroiliac injections have been advocated to help diagnose specific local causes of serious LBP illness. These tests rely on a subjective assessment of pain relief following the attempted anaesthetic blockade of the suspected painful anatomy. It is interesting that the results of these injections do not appear to correlate with the presence or extent of pathologic changes seen in the facet or sacroiliac joint. To date, these tests have not been validated by the recommended methods for the assessment of diagnostic tests. Alternatively, without specific test validation (confirming the presence of a specific disease per se), a test may be useful by improving outcomes through patient selection for specific treatment, that is a test may have utility in the absence of confirmed diagnostic validity. There is some suggestion that careful placebo controlled blocks may improve the outcome of neuroablative techniques to the lumbar facet. So far, however, facet and SI joint blocks have not been shown to improve the outcomes of spinal fusion surgery. There is interest in the use of these blocks in patients being considered for disc replacement surgery to exclude serious pain from the facet joints, which may confound the results of disc replacement alone. This theoretical use has yet to be confirmed.

**Predictors of poor outcomes**

While finding a specific structural process that predicts chronic LBP illness has proven elusive, psychosocial factors have been found to strongly predict future disability and health care utilization for LBP in asymptomatic subjects. Patients with high fear-avoidance of pain, psychological distress, compensation claims, personal injury litigation, and job dissatisfaction at initial evaluation for LBP have poorer outcomes and tend more commonly to develop chronic LBP illness than those without these risk factors. This effect seems accentuated in persons with...
LBP with only degenerative changes found on evaluation, in whom psychological distress and compensation claims are much more common than in patients with definite pathologic or destructive processes.30,31

Specific precipitating activities, unless involving compensation claims, do not appear to be helpful in distinguishing outcomes. When subjects reported LBP episodes arising spontaneously or associated with common activities of daily living, these appeared to have the same risk of evolving into more serious LBP illness as when the LBP episodes followed minor trauma, such as minor falls, lifting injuries, or motor-vehicle accidents. Furthermore, if the person had the perception that the minor trauma event was their own fault, or no one’s fault, the recovery potential was actually better. Conversely, subjects perceiving they have been injured through another’s fault, especially if pursuing compensation, did much worse.32

Surgical strategies for common degenerative conditions

The clinical problem of persistent disabling LBP illness with only non-specific structural findings has proven minimally impacted by most interventions. Non-surgical interventions have been occasionally shown to be more effective than placebo or “usual care” but these effects are most commonly small and often of doubtful clinical relevance.33 While such non-surgical methods are usually of relatively low risk and morbidity, there are some notable exceptions such as the long term non-steroidal anti-inflammatory drugs, chronic poorly monitored and escalating narcotic administration, or repeated corticosteroid administration.

Surgical treatment for back pain is still controversial and by its nature is associated with both real risks and sizable costs. Furthermore, there is little consensus in practice on how to apply surgical technology to this problem and enormous geographical variation in practice patterns across the world.34 In general, there are two divergent clinical approaches to the issue of chronic LBP illness in the absence of serious structural disease. The first has focused on the identification and treatment of an occult, local “pain generator”. This assumes there is a specific patho-anatomic finding in the spine that accounts for the persisting and disabling symptoms independent of psychological, social or neurophysiological co-morbidities, and this can reasonably be expected to be identified and effectively treated.

The opposing view has held that this search for a specific “pain generator” is misplaced. This group has pointed to epidemiologic trends and the poor success in treatments directed at the spine per se. As the local pathology seen on imaging studies is similar in persons doing well with minimal or occasional low back pain as in those with claiming severe pain and disability, the difference in clinical manifestation, by this rationale, is due to other factors, e.g. central pain processes, psychological factors, social disincentives, poor coping strategies, etc. Treatment and prevention according to this approach would be directed at restoring function and supporting adaptive techniques as opposed to medical or surgical treatment of the common spinal changes.

In general, before considering specific surgical treatment for LBP and only common degenerative findings, the patient and surgeon should have a relatively high confidence that the intervention is directed at a specific local pathology and has a good chance of real clinical improvement.

Minimally clinical important differences in spinal surgery outcomes

The concept of a defined minimally clinically important difference (MCID) in spinal disorders has evolved over the last decade. For surgical techniques, involving much greater patient risks, costs and morbidity, the frequently cited MCID developed for pharmacologic testing (a 1–2 point improvement in the pain scale (0–10) or an improvement of 10–15 on the Oswestry scale), is likely too small a change for the magnitude of intervention contemplated with spinal fusion or disc replacement. Pre-operative evaluation of subjects about to have spinal fusion for spondylolisthesis or presumed “discogenic pain” sources indicate this group perceived that such small changes were inconsistent with their expectations and minimum acceptable outcomes (Table 1). Most patients perceived that a minimum improvement more than 25 points on the Oswestry Disability Index (ODI) would be needed to achieve their minimum functional goals; similarly, an improvement of 4 of 10 on a pain intensity scale was considered a minimum acceptable change.35

Surgical treatments of lumbar disc degenerative, annular disruption or spondylosis

Early after the recognition that disc herniation treated with laminectomy and disc removal appeared to be an effective treatment of sciatica, the same decompressive surgery was generally applied to common back pain in the presence of disc degeneration. This approach was remarkable for reported anecdotal successes but much more common failures. By and large laminectomy has been abandoned as a primary treatment of back pain without neurological symptoms due to degenerative changes.36

Currently the three general strategies of surgical treatment used for chronic and severe LBP illness in the absence of serious spinal pathology are commonly considered:

- lumbar fusion by a variety of techniques,
- open surgical methods without fusion (disc arthroplasty, dynamic stabilization),
- percutaneous techniques to alter disc mechanics or nociception (nucleoplasty or intradiscal electrothermal annuloplasty).

Lumbar fusion

Lumbar fusion for LBP due to serious structural disease is clearly effective. Fusion may be dramatically beneficial in the setting of certain fractures, persistent or complicated spinal infections, progressive deformity, demonstrable radiographic instability with spondylolisthesis, etc. Spinal fusion for unstable isthmic spondylolisthesis can return 70–90% of patients to full occupational function with minimal functional impairment and ceasing all narcotic analgesic medication.21,37
The best documented outcomes after lumbar fusion for common degenerative findings without instability or neurological compression is much less impressive. There have been three randomized clinical trials comparing non-surgical treatment to spinal fusion published in the last five years (Table 2). Two of these trials (Brox et al. from Norway, Fairbank et al. from Great Britain), used a cognitive-behavioural model for the non-surgical arms of treatment which appears to be more effective than “usual care” management. Both of these studies utilizing the cognitive behavioural methods showed only small differences between fusion and non-surgical treatments, with some relative advantages to non-surgical management (fewer complications, better coping strategies, possibly better occupational outcomes) and some relative advantages to fusion (marginally better Oswestry Disability scores in one

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<th>Table 1</th>
<th>Minimal acceptable outcomes for fusion surgery in LBP reported prospectively by patients (n = 94).</th>
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<tr>
<td>Minimum acceptable outcome</td>
<td>Pain improvement (VAS 0–10)</td>
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<tr>
<td>4 points improvement (median)</td>
<td>28 points improvement (median)</td>
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<td>2 points improvement acceptable to less than 10%</td>
<td>14 point improvement acceptable to less than 10%</td>
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<th>Table 2</th>
<th>Evidence from RCTs for spine fusion in chronic LBP with degenerative changes.</th>
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<tr>
<td>Study design</td>
<td>Significant exclusion</td>
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<tr>
<td>Brox et al.39</td>
<td>64 patients with chronic LBP (mean 10 years)</td>
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<tr>
<td>RCT: lumbar fusion (1–2 level) vs. “cognitive intervention” and exercise</td>
<td>Widespread “myofascial pain”</td>
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<td>Previous fusion surgery</td>
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<td></td>
<td>Compensation dispute not an issue (Norway)</td>
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<tr>
<td>Fritzell et al.41</td>
<td>294 patients with chronic LBP (mean of 9 years, disabled mean 3 years).</td>
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<tr>
<td>RCT: non-standardized physical therapy vs. lumbar fusion (three types of fusion techniques)</td>
<td>Previous fusion surgery</td>
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<td></td>
<td>Compensation dispute not an issue (Sweden)</td>
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<td>Fairbank40</td>
<td>394 patients (age 18–55) with chronic LBP and whose clinician was uncertain if fusion or non-operative treatment would be effective</td>
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<tr>
<td>RCT: fusion or Graf stabilization vs. “cognitive intervention” and intensive rehabilitation</td>
<td>Previous fusion surgery</td>
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<td>Strong clinical belief that surgery would be highly effective</td>
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in the third RCT by Fritzell et al.\textsuperscript{41} from Sweden, small but statistically significant advantages were seen in the fusion group compared to an unstructured continuance of non-surgical modalities. Nonetheless, high-grade successes were not commonly seen in either group (16% in the fusion group compared to 6% in the non-surgical group) (Table 2).

While there have been no RCTs of fusion vs. non-operative care in the United States, data are available from cohort studies comparing various fusion techniques. Many of these studies include fusion for spondylolisthesis and gross instability in heterogeneous cohorts. Nonetheless, in these studies with more concrete pathologic changes lumbar fusion appears to have better outcomes than in the European RCTs performed for non-specific changes. In the three European RCTs, the ODI improvements ranged from 3 to 13 points for non-operative care and 11–15 points for surgery. In a large US trial for FDA approval of different fusion techniques for a heterogeneous diagnostic group with varying severity of pathologies including spondylolisthesis, the mean ODI outcome was approximately 20–25 points.\textsuperscript{42} A similar range of improvement on the ODI has been seen in other similar FDA studies and prospective cohort studies.\textsuperscript{43} These ranges begin to approximate the minimum acceptable levels of improvement prospectively identified by patients.

However, in the cohort studies which identify only non-specific DDD or “internal disc disease” as the subject population, the outcomes are much more modest. Slozar et al.\textsuperscript{44} found that outcomes after lumbar fusion met the patients’ expectations in only 10% of nearly 100 subjects. Similarly, DeBernard et al.\textsuperscript{45} found satisfactory outcomes were uncommon in subjects having spinal fusion for non-specific findings in a worker’s compensation setting. McKenna et al. found ODI improvements of only 6–15 points for spinal fusion for non-specific MR changes and discography-positive suspected discogenic pain at one or two levels. Only about 20–30% of these subjects met the minimum acceptable outcomes criteria of 4 points VAS and 28 points ODI improvement.

Even in the “best-case” setting of subjects with single-level fusion, normal adjacent segments, and no psychosocial co-morbidities, only 40–50% of subjects meet their minimal acceptable goals when fusion is performed for non-specific degenerative changes and a positive discography response.\textsuperscript{21}

Nucleoplasty and intradiscal electrothermal annuloplasty (IDET)

Some have attempted to treat back non-specific or suspected “discogenic pain” by altering the annulus or disc nucleus by applying a type of ablative energy to these structures. Despite early enthusiastic application and theoretical conjecture, these techniques have failed to prove effective when tested in a controlled clinical trial. A large RCT of IDET by Freeman et al. failed to show any effect in pain improvement, disability, medication intake or occupational status between subjects treated with the IDET device or a sham intervention. Furthermore, the placement of the catheter, supposed to be critical to achieving the desired effect, did not correlate with outcomes upon close review. An RCT by Pauza et al., in subjects with relatively minor LBP, appeared to show only small differences between IDET and sham treatment, despite methodological problems favouring the IDET group. Another study in Australia testing IDET against a sham control was abandoned when detection of differences between IDET and sham groups were calculated to be highly unlikely based on early data analysis. Finally, radiofrequency thermocoagulation of the nucleus was not shown to be more effective than sham treatment in a small RCT.\textsuperscript{46}

While there may be a role for this strategy in the future, there is insufficient evidence to recommend the current treatments tested so far. Given the widespread application of these apparently ineffective interventions, such as IDET, prior to controlled and rigorous clinical assessment, it is clear that cohort studies alone are insufficient to evaluate efficacy of this technology. Future percutaneous surgeries with similar designs should be viewed with healthy scepticism before true efficacy is confirmed with independent randomized controlled trials.

Artificial disc replacement

Treatment of arthritic hip and knee joints with artificial bearing surfaces, that is joint replacement, is a proven orthopaedic intervention. The early history of hip and knee joint replacement surgery was marked by notable and sometimes extraordinary failures. After years of clinical research, relatively stable and durable prostheses have been developed which can be expected to last 15–20 years in a relatively elderly clinical population.

Arthrosis of the spine has been recently treated with artificial disc replacement (ADR) using a variety of prostheses. Clearly the facet arthrosis if present will remain untreated by attempts at mechanical disc replacements. Despite this theoretic limitation, short-term trials have proven encouraging in so far as early complications have been infrequent and motion appears to be maintained for several years at least, in many patients. There is a theoretical advantage to continuing motion as it may decrease the rate of disc degeneration at segments adjacent to the surgery compared to fusion. There is obviously a native progression to adjacent segment disease and not all disc degeneration is seriously symptomatic. The advantage, if any, from an ADR over a fusion, on this basis will require a long and carefully controlled clinical assessment. The joint constraint characteristics, mobility, bearing surface composition vary in different designs and thus far no head to head comparison is available to determine whether one type is superior to another.

Clinical results comparing the outcome of ADR and fusion for non-specific LBP and degenerative changes have been inconclusive. By most parameters the outcome of these trials have shown little difference in functional outcomes, pain intensity, medication intake or occupation disability.\textsuperscript{47–49} Approximately 50% of the subjects in both US and UK trials appear to be clinical failures despite rigorous entry criteria.\textsuperscript{47,49} Long-term follow-up from these trials remains to be examined. A 17-year follow-up from the early European experience with the Charite device has questioned the viability of motion over time and suggested the persistence of motion may not be clinically beneficial so far as pain intensity.\textsuperscript{50}
In these early trials the problems of prosthetic loosening, implant wear and reaction to particle debris have not proven to be common. However, since the age of implantation of these devices is only about 40 years, much younger than hip or knee arthroplasty patients, the concern for long term outcomes is real. If after widespread implantation even 10–20% of this group develop aseptic loosening, particle-mediated inflammatory disease, local root-irritation or segmental collapse resistant to primary reconstruction, there may be a looming and potentially catastrophic clinical problem in the future. While there are very enthusiastic advocates of this technology, patients need to be advised that the outcomes do not appear clearly better than the marginal results of fusion techniques and the long-term risks remain poorly examined at this stage.

Future directions

In the near future, new technologies for surgical treatment of non-specific LBP illness may include biological modification of disc metabolism, alteration of disc genetic expression to change mechanical properties, synthetic nuclear augmentation devices as well as combined facet and disc mechanical replacements. The ability to perform even complex surgical procedures using minimally invasive techniques will undoubtedly continue to evolve. The balance of benefit to risk with many of these newer technologies may not be apparent in early applications. For instance, the use of biological fusion enhancing drugs may have short-term beneficial effects on arthrodesis but the long-term metabolic, immunologic or possibly neoplastic effects are unknown. Similarly, drugs designed to enhance disc metabolism may transiently increase the disc hydration or MR signal but may lead to more rapid apoptosis of the activated cells and accelerated disc degeneration.

Regardless of the technological advances for intervention, the central question behind any of these strategies however remains. In patients with common degenerative findings alone, why are some doing very well, some are minimally incapacitated from all common daily activities? The diagnosis of LBP may be a larger problem than choice of intervention. If much of the severe LBP illness associated with only minor changes of the lumbar spine is, in fact, primarily a function of a generalized pain intolerance, or is an expression of psychological illness such as depression or anxiety, or is secondarily driven by compensation issues, dysfunctional social adaptation or poor coping skills, little effect will be seen by intensifying efforts to eradicate local, benign pain processes in that subgroup.

Practice points

- There is poor correlation between MR findings of spinal degenerative changes and symptoms in adults
- Most people function well despite significant and progressive spinal degenerative changes
- The cause of serious LBP illness in the absence of serious spinal diseases such as instability, infection or neoplasm is not well understood and non-structural factors such as central pain intolerance, psychological distress, social and economic issues of compensation and participation, appear to act as co-morbidities to LBP illness impairing recovery
- In RCTs of surgical vs. non-operative care, lumbar fusion surgery for common degenerative changes appears to offer only limited relative benefits over intensive rehabilitation. Cohort studies of highly selected subjects have somewhat better outcomes
- Artificial disc replacement has approximately the same outcomes as fusion in short-term studies but the long-term risks of prostheses placement in relatively young patients remains a concern

References


