Failed Back Surgery Syndrome

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Causes of Back and Leg Pain

Identifiable causes are rare:

- Osteomyelitis
- Epidural abscess
- Tumours
- Ankylosing spondylitis

Lumbar disc herniation and spinal stenosis cause back and leg pain
Facts

• Almost 50% of patients with structural abnormalities on plain x-rays do not have back pain (disc degeneration, facet joint degeneration, spondylolisthesis, spina bifida, transitional vertebrae, Scheuermann’s “disease”, etc.)
• The majority of back pain sufferers have some degree of degenerative spinal disease. (Back pain has a 30-50% one month prevalence rate from age 15)
• Labelling patients with poorly-defined syndromes can make them worse
• No scientific admissible evidence exists for a link between radiographic findings and pain
• There is no pre-operative test that reliably predicts the response to surgery (e.g. root blocks, discography, flexion-extension lateral x-rays)
Definition of Failed Back Surgery Syndrome

Persistent low back pain or leg pain despite previous low back surgery

Imprecise term encompassing a heterogeneous group of disorders that have in common pain symptoms after lumbar surgery.

• Patients remain severely disabled with chronic long term disability

• Temporary relief for a few months then recurring symptoms (“honeymoon” period)

Unique. No other area of surgery has the equivalent term. What about Failed Neck Surgery Syndrome?
Origin

Unclear when the term was first introduced

1993 Follett KA, Dirks BA. Etiology and Evaluation of the Failed Back Surgery Syndrome. Neurosurg Quart; 3(1); 40-59 (1993)


1987 Law JD. Targeting a spinal stimulator to treat the ‘failed back surgery syndrome’. Appl Neurophysiol; 50(1-6); 437-8 (1987)
10 - 40% of patients undergoing lumbar surgery “fail”

Assuming 0.05% of the population undergo back surgery per year (5/10,000), that equals 30,000 operations in the UK. If only 20% fail (10% - 40%), that is generating 6,000 patients/year with FBSS.

1998 - 2008 - Spinal fusion operations in the USA increased from 174,000 to 413,000/year.\(^1\) 30% will undergo re-operation within 5 years.

The incidence of spinal fusion in Canada is 80/100,000/year.

No properly conducted study indicates a good or excellent result for fusion surgery as more than 60%, and only 30% for repeat surgery.

Return to work: 40% for anterior fusion operations and only 16% for posterior fusion operations.\(^2\) (Much worse in repeat surgery)

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2. Greenough CG et al. Instrumented posterolateral lumbar fusion. Results and comparison with anterior interbody fusion. Spine; 23 (4); 479-86 (1998)
### Surgical Failures

<table>
<thead>
<tr>
<th>Unavoidable</th>
<th>Unjustifiable</th>
<th>Unintentional</th>
</tr>
</thead>
</table>
| Recurrent Disc Prolapse – 7%  
Discitis  
Adjacent segment disease  
Post-compressive Radicular Dyaesthesia | Fusion for Axial Back Pain  
Unproven Devices | Nerve Root injury  
Non-fusion  
Wrong level |
Lumbar Disc Prolapse
Right L4/5

Sagittal T2

L4/5 Axial T2
Lumbar Disc Prolapse
9/12 post discectomy - Recurrent prolapse

Sagittal T2

L4/5 Axial T2
Lumbar Fusion

Unilateral left L4/5 fusion for post decompression instability pain

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Lumbar Fusion

L4 Pedicle Screw

L5 Pedicle Screw

ESRA 2017
Lumbar Fusion
Revision of Pedicle Screws

L4 Pedicle Screw  L5 Pedicle Screw
Causes of Failure

“Unjustifiable” - The wrong operation in the wrong patient for the wrong reason

Inappropriate patient selection, irreversible nerve injury and inadequate surgery.

- Diagnosing and treating clinically irrelevant pathology (e.g. Black disc, HIZ, non-compressive disc herniation - 76% of patients without any symptoms have a disc hernia on MR scans*)
- No scientific rigour in assessing efficacy of surgery or other techniques
- Where evidence exists (Cochrane Back Review Group for Spinal Disorders - meta-analyses), ignored by spinal surgeons
- Commercial pressures to use new technology without RCTs
- Disregard for the importance of psychosocial factors and the social and cultural factors that influence return to work after surgery

*Boos et al. The diagnostic accuracy of magnetic resonance imaging, work perception, and psychosocial factors in identifying symptomatic disc herniations. Spine 20 (24), 2613-25 1995
Psychological Factors

Waddell 1979
Demonstrated that failed spine surgery patients compared to failed total hip patients had much more pain on a VAS scale, significantly more disability, pain drawing magnifications, and inappropriate signs of pain behaviour and fear avoidance.

“Yellow Flags”
- Poor health beliefs
- Never pain free
- Fear of activity/movement
- Previous long disabling back pain attacks
- Frequent emergency treatment of back pain
- Whole body part numbness
- Whole extremity giving way

When present to a considerable degree, these signs will predict poor results, particularly with repeat surgery.

Compensation; Employment status
<table>
<thead>
<tr>
<th></th>
<th>APLD</th>
<th>Instrumented Posterior Fusion</th>
<th>Anterior Cage Fusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventors first report</td>
<td>90%</td>
<td>95%</td>
<td>90%</td>
</tr>
<tr>
<td>Subsequent case series</td>
<td>80%</td>
<td>75%</td>
<td>80%</td>
</tr>
<tr>
<td>Prospective case-control &gt; 2 years follow-up</td>
<td>70%</td>
<td>60%</td>
<td>60%</td>
</tr>
<tr>
<td>RCT, blinded unbiased &gt; 2 years follow up</td>
<td>40%</td>
<td>40%</td>
<td>?</td>
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</table>

Can the Incidence of FBBS be reduced?

Is there a better term for FBBS? Chronic Post-surgical back and leg pain (CPSBLP)?

The number of cases being generated could be reduced if surgeons:

• Selected patients on the basis of legitimate pathology and with a better knowledge of the psychosocial factors involved
• Had a good knowledge of the reputable science and available research
• Independently audited and registered their cases
• Considered the minimum surgery required to address the patient’s problem
• Avoided unnecessary risks and kept complications to a minimum
• Introduced new technology in a more objective and evidence-based manner
• Considered the role of conservative strategies and neuromodulation rather than repeat surgery in some of their patients

“There is strong evidence that LF is not more effective than conservative treatment in reducing perceived disability because of CLBP among patients with degenerative spinal diseases. It is unlikely that further research on the subject would considerably affect this conclusion”

Saltychev 2014 Meta-analysis 1990 - 2013

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The Epidemiology of Failed Back Surgery Syndrome in the United Kingdom

- Precise estimates of the epidemiology and healthcare utilisation of patients with FBSS in the UK have not been published.

- The key objectives of this study are:
  - to identify cases of FBSS in administrative healthcare data and estimate incidence over the period 1997-2012
  - to estimate the cost to the National Health Service (NHS) of caring for FBSS patients annually from 2007-2012.

- Such data are needed to inform policy and practice in the rapidly expanding field of lumbar surgery in the UK.

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Clinical Practice Research Datalink

- CPRD is a well-validated computerised database of anonymised longitudinal medical records from primary care linked with the Hospital Episode Statistics (HES) database.
- CPRD covers approximately 8% of the UK population and is broadly demographically representative.
Study Population

- In total, we identified 12,900 adults in CPRD who underwent initial lumbar surgery from 1997-2012 and had at least 12 months post-index surgery follow up data.
- 10,901 patients had at least two years of follow up data, allowing for more complete assessment of evidence of FBSS.
UK lumbar surgery rates more than tripled in CPRD between 1997 and 2012, largely owing to increases in decompression and fusion surgery rates:

**Incidence Rate Per 10,000 by Type of Surgery**

- decompression
- discectomy
- fusion
- other

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In the two years following lumbar surgery, 55.3% of patients had some combination of events indicating that the index surgery did not resolve their pain.
• Among lumbar surgery patients in CPRD, 5.3% of patients had further lumbar surgery within 3-24 months or had a spinal cord stimulator or intrathecal drug delivery system implanted at some point.

• Among those who received further surgery or surgical treatment, 23.9% sought ongoing treatment for pain and 78.5% continued to receive pain medication in the two-years following the index surgery.

• Among those who did not require further surgery or surgical treatment, only 9.4% sought ongoing treatment for pain but 50.6% continued to receive pain medication in the two-years following the index surgery.
The Epidemiology of Failed Back Surgery Syndrome in the United Kingdom

<table>
<thead>
<tr>
<th>Combination of events</th>
<th>Percent of all cases</th>
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<tbody>
<tr>
<td>A alone</td>
<td>1.2%</td>
</tr>
<tr>
<td>B alone</td>
<td>40.4%</td>
</tr>
<tr>
<td>C alone</td>
<td>1.8%</td>
</tr>
<tr>
<td>A+B</td>
<td>3.4%</td>
</tr>
<tr>
<td>A+C</td>
<td>0.1%</td>
</tr>
<tr>
<td>B+C</td>
<td>7.1%</td>
</tr>
<tr>
<td>A+B+C</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

\[ FBSS = A \text{ alone} + C \text{ alone} + (A+B) + (A+C) + (B+C) + (A+B+C) = 14.9\% \]
Conclusions

- Lumbar surgery has become increasingly common in the UK in recent years.
- Previously estimated rates of failed spinal surgery for the UK range from 10-40% [1], but these rates include cases that may or may not meet reasonable criteria for FBSS.
- As there is no diagnosis code commonly used for FBSS and some disagreement in the literature on the elements required for diagnosis, identifying cases using administrative data presents a challenge.
- A combination of evidence of sustained pain (min 6 months) from 3-24 months following index surgery and/or further lumbar surgery or other treatment for lumbar pain may be required to identify cases of FBSS.

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Therapeutic Options

• All the options for the treatment of LBP and neuropathic leg pain:
  • Functional Restoration Programmes
  • Pain Management Programmes
  • Psychological interventions e.g. CBT
  • Pharmacology & Invasive interventions

  – Has a further surgical target been excluded?

• Neuromodulation
  • “the alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body.” [INS]
Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin

Technology appraisal guidance [TA159] Published 2008

• Spinal cord stimulation is recommended as a possible treatment for adults with chronic pain of neuropathic origin if they:
  • continue to experience chronic pain (measuring at least 50 mm on a 0-100 mm visual analogue scale) for at least 6 months despite standard treatments, and
  • have had a successful trial of spinal cord stimulation as part of an assessment by a specialist team.

• Treatment with spinal cord stimulation should only be given after the person has been assessed by a specialist team experienced in assessing and managing people receiving treatment with spinal cord stimulation.

• SCS for chronic low back pain

• Dorsal Root Ganglion (DRG) stimulation

• ITDD (Intrathecal Drug Delivery)
Sources


https://www.nice.org.uk/guidance/cg173

http://thepainsource.com/innervation-of-lumbar-facet-joints/

http://thepainsource.com/multifidus-atrophy-after-lumbar-radiofrequency-neurotomy/

http://www.sheffieldbackpain.com/professional-resources/learning/in-detail/yellow-flags-in-back-pain

http://www.bmj.com/content/326/7388/535

https://www.keele.ac.uk/sbst/startbacktool/

https://www.nice.org.uk/guidance/ta159