Evidence update:

Efficacy and Safety of Interspinous Spacer Devices

Feb 2016

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1 Purpose & background

The Clinical Advisory Panel has asked the Clinical Knowledge Management team to review recent evidence of the effectiveness and safety of interspinous spacer devices (ISD).

ISD are small devices implanted between the vertebral spinous processes to open the neural foramen and decompress the nerves. ISD are used to treat mild and moderate intermittent neurological claudication from spinal stenosis. ISD are positioned between two spinal processes and are either attached via a function of the device’s shape or by being tied to the spinous processes. In spinal stenosis, ISD relieve pain and other symptoms by limiting excessive spinal extension and thus lessening the pressure on the spinal cord [1] [2] [3].

There are different types of ISD but they are functionally equivalent such as WallisTM, DiamTM, Viking, X-STOP, Coflex. The devices can be made of metal (e.g., titanium alloys), polymers (e.g., polyetheretherketone), bone allograft and elastomeric compounds [1].


The current (2012) ACC purchasing recommendation is “Do not purchase” [3]. It was noted that ISDs may be effective in the short to medium term for carefully selected patients. Those patients that may be suitable for ISDs are unlikely to be ACC clients.

The purposes of this scan are:

1. To locate any recent (2012 onwards) meta analyses, systematic reviews or evidence based guidelines on ISD and summarise their conclusions.
2. To identify any existing overseas policies / guidelines on funding ISD.

2 Methods

The following sources were searched in May 2015 using appropriate keywords (see appendix for search strategies):

- Medline & Embase databases
- Aetna & Cigna (US health insurers) websites
- Google & Google Scholar

The findings are described in section 3 below.

Inclusion criteria: Only published systematic reviews and relevant clinical guidelines based on systematic reviews were considered for this evidence scan. The period of search was July 2012 till May 2015. For background information and comparison, funding policies from other insurance companies were also considered.

Only papers published in English were considered.

Exclusion criteria:

The following types of studies were excluded: Primary studies, observational studies, case reports, retrospective studies and narrative reviews. Also excluded are product brochures, publications in languages other than English, conference presentations and proceedings.
## 3 Findings

### 3.1 Evidence of effectiveness

Three meta analyses/systematic reviews, two guidelines and two insurer policies were identified:

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| [4] Hong et al (2015) | This is a meta-analysis to evaluate the efficacy and safety of interspinous process distraction devices (IPD) compared with open decompression surgery (ODS) in lumbar spinal stenosis.  
21 publications met the inclusion criteria for this meta-analysis (n=54,138). Types of IPD in the included trials were not identical (they included X Stop, DIAM, Aperius, Coflex, Wallis and SPIRE). In the majority of the included studies follow up was up to 2 years.  
Outcomes studied: improvement rate for pain and function, specific operation related complication occurrence rate and reoperation rate. Other results included pain Visual analog scale score, Oswestry Disability Index score, operation time, peri operation blood loss volume and hospitalization time.  
Concludes that “the results indicated that IPD has better effects and less complication than ODS. However, because of the higher reoperation rate in IPD than ODS, we failed to conclude that IPD could replace ODS as golden standard but may be a viable alternative in treating lumbar spinal stenosis”. | The majority of the included studies were prospective cohort studies (which have the potential for methodological bias & selection bias); only 3 were randomized clinical trials. However, the cohort trials were noted to be of high quality. Cost – benefit analysis could not be done. The authors have not provided a conclusive comment regarding safety/ overall cost of treatment.  
There were high rates of reoperation in the observed follow up period in 7 trials (16.15% in the IPD group versus 8.73% in the ODS group).  
The results suggest that IPD may be a viable alternative in a highly selected group of patients with mild to moderate stenosis. |
19 publications (17 trials) were included (n=1,554)  
Comparison was done for various surgical methods. Of relevance are the following comparisons (in 4 trials with n= 641) :  
- Decompression plus fusion vs interspinous spacer devices (ISD)  
- Laminectomy / laminotomy v ISD  
ISD in the studies were X-Stop and Coflex. The follow up periods ranged from 12 – 24 months.  
Outcomes studied varied across studies but included leg pain, physical function, Oswestry | All the included studies are randomised controlled trials, most of them graded as low to moderate quality.  
The authors acknowledge the methodological limitations such as lack of blinding in all of the included trials, poor reporting of data and absence of data regarding adverse effects in all included studies.  
Overall, of the various surgical modalities investigated, ISD has the highest reoperation rates for the period observed (i.e. 24 months). Given the methodological limitations it is postulated that the true rates of adverse effects /... |
Disability Index, operation time, blood loss, complications, reoperations and hospitalization.

The forest plots show that there was no difference in pain reduction and disability at short term (less than 12 months) follow up between decompression vs ISD group. Also there was no difference in pain reduction at long term follow up (12 months or more) between decompression vs ISD group and decompression +fusion vs ISD group. There is moderate quality evidence that ISD are slightly superior to decompression +fusion on disability outcomes in the long term.

Concludes that “Overall, the quality of the available evidence ranged from "high" to "very low" revealing non-significant differences across surgical techniques for lumbar spinal stenosis, and a small, but clinically debatable, benefit of ISD devices compared to decompression plus fusion...
Although the operation using ISD is quicker, these devices are more expensive than conventional bony decompression and are associated with higher revision surgeries. We, therefore, question the use of decompression plus fusion and the safety of ISD in the management of patients with lumbar spinal stenosis.”

This paper investigates the effectiveness of dynamic interspinous spacer devices (ISD) such as X STOP, Coflex, DIAM and Aperius in the treatment of lumbar spinal stenosis as compared to traditional decompressive surgery (TDS).

5 publications were included: 2 RCTs and 3 non randomized prospective studies comparing ISD (n=204) and TDS (n=217).

Follow up duration was at least 12 months and up to 24 months.

Outcomes studied include low back pain, leg pain, the Oswestry disability index (ODI) and the Roland disability questionnaire (RDQ), complications and incidence of reoperation.

Pooled analysis showed no significant difference between the ISD and TDS groups for VAS scores for low back pain and leg pain. Two studies each reported no significant difference in the ODI and RDQ scores.

Five studies met the inclusion criteria. Of the included studies, only two are randomised controlled trials, the rest being non randomised prospective studies. However the quality of the RCTs is low to medium.

Sample sizes in the included studies are relatively small.

The authors’ summary of the assessment of risk bias clearly demonstrates lack of blinding in all except one of the included studies; potential confounders are not outlined nor are adequate adjustments made to account for the confounders in the included studies.

*cost of each ISD device is at least €2,000 (£1,704; $2,756), as reported by Moojen et al.
There was no significant difference in incidence of post-operative complications for the period of observation.

The incidence of reoperation was reported in 3 studies. The incidence of reoperation was significantly lower in the TDS group. Further subgroup analysis was done based on the ISD surgical method (minimally invasive-MI and open surgery-OS) – the higher reoperation rate was not related to surgical method.

The authors conclude that “Although patients may obtain some benefits from ISD implanted through a minimally invasive technique, ISD use is associated with a higher incidence of reoperation and higher cost. The indications, risks, and benefits of using an ISD device should be carefully considered before surgery.”

** ISD insertion has been associated with spinous process fracture, implant dislocation, and heterotopic ossification.

### Guidelines

| [7] North American Spine Society (NASS) Guidelines for degenerative lumbar spinal stenosis (2011). | The NASS guidelines provide evidence-based recommendations to address key clinical questions surrounding the diagnosis and treatment of different spinal conditions. As regards ISD for the treatment of lumbar spinal stenosis the recommendation is “there is insufficient evidence at this time to make a recommendation for or against the placement of an ISD spacing device in patients with lumbar spinal stenosis.” As regards ISD for the treatment of degenerative spondylolisthesis the recommendation is “there is insufficient and conflicting evidence to make a recommendation for or against the efficacy of ISD versus medical/ interventional treatment in the management of degenerative lumbar spondylolisthesis patients”. See https://www.spine.org/ResearchClinicalCare/QualityImprovement/ClinicalGuidelines.aspx for full guidelines |
### 4 Adverse effects

The results from the systematic reviews included in this evidence scan indicated that ISD had lower rates of specific operation-related complications (less hospitalisation time, less peri-operation blood loss and shorter operation time) and higher rates of reoperation than open decompressions [4] [5] [6].

Other sources have also identified complication, such as higher rates of fractures of spinous processes than previously reported for ISD [9].

### 5 Conclusions

The evidence scan showed that there is low quality evidence of positive results with ISD but there is a greater volume of evidence of adverse effects as compared with traditional decompression surgery for spinal stenosis. Higher risk of reoperation is consistently reported in the literature, along with other issues such as higher incidence of spinous process fractures.

There are occasional requests for ISD for generally younger people with a diagnosis of pain from the posterior annulus or from the facet joints but there is very little published evidence to support the use of ISD in the younger population with these conditions. The participant characteristics of the majority of studies on ISD show the mean age of participants to be greater than 60 years.

In light of the absence of new good quality studies of effectiveness and the increased reports of adverse effects, there is no change to the 2012 purchasing recommendation [2] [3]. It would therefore seem appropriate for ACC to continue to follow the 2012 recommendation until more evidence becomes available.
6 Bibliography


7 Appendix

7.1 Search strategies

The search was conducted by an information specialist from the ACC Evidence Based Healthcare team. The search strategy run on the Medline and Embase databases (Ovid platform) is shown below. The Google search used free text terms as appropriate.

Only papers published in peer reviewed English language journals were included.

1. exp lumbar vertebrae/ or exp lumbar spine/ or exp spinal disease/
2. (spine*.mp. and ('stenosis'/de or instability.mp.)) or lss.mp. or (herniat* and (disc* or disk*)).mp. or 'spondylolisthesis'/de or 'spondylarthrosis'/de or (degenerative and disc and disease).mp. or (degenerative and disk and disease).mp. or (facet.mp. and 'joint'/de and arthritis.mp.) or (modic and i and lesion).mp. or (static and disorder).mp. or (facet and arthropathy).mp.
3. lumbar disc hernia/ or spine instability/ or intervertebral disk degeneration/ or intervertebral disc hernia/ or exp spine surgery/ or exp lumbar spine/ or exp lumbar disk/ or exp spine stabilization/
4. or/1-3
5. ((interspinous and (implant* or device* or distract*)) or ((dynamic or elastic) and (neutrali?ation or stabili?ation)) or 'non fusion' or 'X STOP' or (wallis and system) or (minns and silicon) or coflex or (intervertebral and assisted and motion) or diam or fixano).mp.
6. (interspin$ or dynamic stabili$ or "X STOP" or wallis or minns or coflex or diam or fixano or dynesys).mp. or ("x stop" or "x-stop" or wallis or diam or coflex or "in-space" or superion or aperius or flexus).ti,ab.
7. 5 or 6
8. 4 and 7
9. limit 8 to (english language and humans)
10. limit 9 to yr="2012 -Current"
11. remove duplicates from 10
7.2 Results of the updated literature search (July 2012 till April 2015)

The following papers were identified in the literature search, but were excluded from the current evidence scan as they are primary studies, case studies, expert commentaries or narrative reviews. Observational and retrospective studies were excluded except where they focus on adverse events and complications.

7.2.1 Primary studies: RCTs and other controlled trials


7.2.2 Adverse events, complications & device failure


7.2.3 Expert commentaries & narrative reviews


7.3 Documents provided by the neurosurgeons for ACC to consider

A list of documents was provided by the external neurosurgeons for ACC to consider. These documents include papers presented at conferences and published by the developers of the devices, including product brochures. The majority of papers submitted were presented or published prior to 2012. There are only two papers published during the inclusion period of this review (2012 onwards). These papers focus on the issue of adjacent segment degeneration following ISS and do not address the question of effectiveness of ISD hence they are excluded from the evidence scan. Product brochures and papers provided by the developers of the device do not meet inclusion criteria as there is a risk of inherent bias towards favourable outcomes in industry sponsored data/research.

The list of documents provided are available from Knowledge Management Team (in an excel spread sheet) and will be made available on request.

7.4 New Zealand Orthopaedic Spine Society perspective on the use of interspinous spacers for ACC patients

ACC has consulted with New Zealand Orthopaedic Spine Society (NZOSS) for their perspective on the use of Interspinous spacers for ACC patients which is stated here.

“NZOSS see limited indications for the use of interspinous spacers for ACC patients. This is reflected in the almost non-existent use by Orthopaedic Surgeons in recent years. The most acceptable indication is for single level spinal stenosis in patients whose symptoms are improved by lumbar flexion and are considered medically unfit for a lumbar decompression under GA (particularly if the spacer is able to be inserted under LA). While some (often industry supported) studies have shown efficacy for such devices in this setting other results have been less convincing. Almost universally studies have noted a higher complication and secondary surgery rate with interspinous spacer use over traditional surgical decompression. No conclusive data exists for the use of interspinous spacers for other clinical scenarios.”