Artificial Discs: Applications to Cervical and Lumber Spinal Surgery for Degenerative Disc Disease

Health Technology Literature Review

Completed March 2004
Disclaimer

This health technology scientific literature and policy review was prepared by the Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care for the Ontario Health Technology Advisory Committee and developed from analysis, interpretation and comparison of scientific research and/or technology assessments conducted by other organizations. It also incorporates, when available, Ontario data, and information provided by experts and applicants to the Medical Advisory Secretariat to inform the analysis. While every effort has been made to do so, this document may not fully reflect all scientific research available. Additionally, other relevant scientific findings may have been reported since completion of the review.

Please contact MASInfo@moh.gov.on.ca if you are aware of scientific research findings that should inform the report or would like further information.

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Executive Summary

Purpose

Surgical options for cervical and lumbar spinal surgery to treat degenerative disc disease have increased significantly over the last decade. This review is intended to summarize the evidence of safety and effectiveness of artificial disc devices for cervical and lumbar spinal surgery, with particular attention to those devices licensed for use in Canada.

The Technology

Spinal surgery approaches to degenerative disc disease (DDD) draw on two apparently diametrically opposed perspectives: fixation and preservation of spinal motion. Proponents of fixation cite the sharing of loads that is possible by internally fixing the segments on either side of the degenerated disc. Spinal fusion, whether by anterior or posterior approach is guided by this perspective.

Advocates of arthroplasty, joint replacement with an artificial disc, cite the preservation of motion between adjacent spinal segments as the chief advantage of devices and procedures they deploy. For the purposes of this review, artificial disc technologies are those that propose an alternative to spinal fusion with preservation of some spine motion. These devices are further categorized as intervertebral prostheses (IVP) and technologies that replace only the nucleus of the disc (NRD).

Review Strategy

Published literature identified through searches of MEDLINE and EMBASE was supplemented with additional peer-reviewed publications identified following review of the results of the MEDLINE and EMBASE searches.

Summary of Findings

IVP devices have been widely used in Europe and Asia. Safety data suggest that events are primarily those associated with any surgery to the spine. Based on the limited reports in the literature, neither IVP device failure or debris production are likely to occur. Two IVP products are currently approved for use in Canada.

NRD products are newer, target less severe disease, and have not been sufficiently evaluated to draw any conclusions regarding safety or efficacy. None are currently approved for use in Canada.

The choice of IVP over spinal fusion reflects a significant conceptual and philosophical divide among spine surgeons. Comparative efficacy data for IVP and spinal fusion are at present sparse, but are expected within the coming 12-24 months for three IVP products reviewed here: SB Charite III, Bryan Cervical Disc and ProDisc II.
Issue

In October 2003, the Ontario Health Technology Advisory Committee prioritized an evaluation of the evidence of safety and effectiveness of artificial disc devices for cervical and lumbar spinal surgery, with particular attention to those devices licensed for use in Canada.

Background

Clinical Need: Target Population and Condition

Degenerative disc disease (DDD) is defined in terms of anatomic, biomechanical, radiological and clinical changes, most frequently noted in the lumbar or cervical spine. DDD is somewhat of a misnomer as it is not a disease per se, but rather a degenerative process that may cause clinically evident symptoms in some people. The symptom most commonly reported by patients is pain, exacerbated by activities such as sitting that increase loads on the intervertebral discs. With the growth of magnetic resonance imaging, radiologic evidence of DDD has been described in rough proportion to age i.e. 40% of people at age 40 rising to over 80% among people over age 80. While imaging techniques are a potentially valuable tool, their use has added to diagnostic uncertainty due to false positive findings, since not all persons with radiologic DDD will report pain or other symptoms.

Surgical options for cervical and lumbar spinal surgery have increased significantly over the last decade. Data from the United States indicate a rapid increase in the number of spinal fusion procedures, most commonly for the indication of symptomatic degenerative disc disease. In the United States, the total number of spinal fusion procedures roughly quadrupled from approximately 65000 in 1993 to upwards of 250000 in 2002. (1) has risen roughly fourfold since 1993. Hardware expenses alone are estimated at US$2.5 billion.

Based on OHIP data, approximately 2000 spinal fusion procedures are performed in Ontario annually. Most are lumbar fusions. This number is expected to grow in the coming decades as the population of older Ontarians grows and thus, the number of surviving people with clinically significant DDD increases. In Ontario, spinal fusion surgery is overwhelmingly performed by physicians trained in either orthopaedics or neurosurgery.

Spinal surgery approaches to DDD draw on two apparently diametrically opposed perspectives: fixation and preservation of spinal motion. Proponents of fixation cite the sharing of loads that is possible by internally fixing the segments on either side of the degenerated disc. Spinal fusion, whether by anterior or posterior approach is guided by this perspective.

Advocates of arthroplasty, (joint replacement), cite the preservation of motion between adjacent spinal segments as the chief advantage of devices and procedures they deploy. In addition, several new devices have been proposed or approved that seek to marry the two perspectives via what may be termed a motion-preserving spinal fusion.

Artificial discs are not a new technology in that the first study on artificial discs was published in 1955. (2) Over 60 patents are reported to have been taken out in the United States on various artificial disc products but many if not most have failed to yield commercially available medical devices. (3)
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For the purposes of this review, artificial disc technologies were deemed to be those that propose an alternative to spinal fusion in that some spine motion is preserved. These devices are further categorized as intervertebral prostheses (IVP) and technologies that replace only the nucleus of the disc (NRD). While an effort was made to provide a comprehensive overview of the devices and technologies in this area, priority has been given to those approved for marketing in Canada or commercially available in other OECD jurisdictions.

Artificial Disc Products

Discussion and consideration of policy options for artificial disc products is complicated by the marketplace reality that there is no single artificial disc product. The products currently available can be categorized into two broad classes: intervertebral prostheses (IVP) and nucleus-replacement devices (NRD).

The human intervertebral disc is composed of a core, the nucleus, surrounded by a fibrous ring, the annulus. The literature suggests a consensus that NRD products are only suitable for moderate degeneration since their functioning relies on the presence of an intact annulus of the intervertebral disc. With more severe degeneration, IVP devices would be indicated. The severity of anatomic degeneration does not appear to have been consistently correlated with clinical symptoms. (4)

Regulatory Status

As of December 29, 2003, 2 artificial disc products were licensed for use in Canada (Table 1).

Table 1: Artificial disc products licenced for use in Canada as of December 2003

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>MANUFACTURER</th>
<th>LICENSE DATE</th>
<th>INDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>SB Charite III</td>
<td>Link Spine Group</td>
<td>7 Oct 2003</td>
<td>Lumbar spine</td>
</tr>
<tr>
<td>Bryan Cervical Disc</td>
<td></td>
<td>6 May 2003</td>
<td>Cervical spine</td>
</tr>
</tbody>
</table>

Media reports of ongoing investigational work in Canada was identified for one NRD: Raymedica’s PDN-SOLO product. (5) As of January, 2004, Health Canada confirms that this device is under investigation in Canada. (6)

Literature Review on Effectiveness

Objective

This literature review addresses two objectives: to summarize safety and efficacy information, including comparative efficacy, of artificial disc products categorized as either intervertebral prostheses or nucleus-replacement devices.
Questions to be answered

1) What information is available regarding the safety, including device failure, of artificial disc devices?
2) How do outcomes with artificial disc devices compare to those with alternative approaches, particularly spinal fusion?

Methods

A search of the literature from Medline and Embase covering the period 1966 through November, 2003 yielded 438 citations. Most of these were basic science papers or pre-clinical animal studies. 130 of the original 438 were selected for further review. Additional citations were identified from the references of papers identified in the initial search.

For question 1, the safety data are drawn from published papers. These safety data are summarized in the results section.

For question 2, randomized controlled trials (RCT), non-randomized comparative trials and case series were identified. For several products, multiple reports of the same patient group were identified. In these cases, efforts to identify the most comprehensive report were made. A total of 9 studies were selected for final review and are summarized below.

Results of Literature Review

Safety - Intervertebral Prostheses

Appropriately assessing the safety of IVP devices would logically entail a comparison of rates of complication to alternative surgical treatments for DDD, particularly spinal fusion. Given the profusion of devices and surgical techniques, it is perhaps unsurprising that no reports of overall rates of complication for all forms of spinal surgery for DDD were identified.

Conceptually, any device requiring surgical intervention yields two types of risk: that attributable to the surgical approach to the relevant anatomic site (e.g. lumbar or cervical spine), and that attributable to the device itself. Thus, case series reviews of pedicle screw fixation for spinal fusion include reports of screw misplacement (7) and cervical radiculopathy due to excessive screw penetration. (8) Similarly, reports from case series of interbody fusion cage devices include dural laceration (9) and reoperation for interbody cage repositioning. (10)

Artificial disc devices of either type would have zero risks of either of any of these events but would have potentially non-zero risks of device failure. This distinction between device-specific risks and risks associated with any spinal surgery for DDD may also be unclear where different devices require different surgical approaches. In the material that follows, all identified complication data have been included, followed by a narrative that endeavours to distinguish between device-associated risks and reoperation rates, and events generally attributable to spinal surgery for DDD, regardless of device.

SB Charite III (SBC)

The SBC product is the third generation product and, since its initial version, has been implanted in over 5000 patients to date, mainly in four countries: the UK, the Netherlands, France and Germany. (4) The
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device includes an ultrahigh molecular weight polyethylene component, but wear-related debris is reported to not occur. (11) Non-human primate studies have both confirmed the absence of debris and the absence of cytokines, (inflammatory mediators detectable in blood) that could be indicative of an inflammatory reaction triggered by device debris. (4) The literature review did not identify any reports of complete device failure. (12)

Table 2, excerpted from a 2003 publication, (12) summarizes reported complications from case series. Most are similar to those from case series of spinal fusion surgery and associated with the approach to the anatomic location, rather than the device itself.

Table 2: Summary of reported complications from case series studies using SB Charite III (SBC) product, to November 2003

<table>
<thead>
<tr>
<th>Complication</th>
<th>Patients (N)</th>
<th>Events (N)</th>
<th>Event Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neurological, temporary</td>
<td>50</td>
<td>7</td>
<td>14.0%</td>
</tr>
<tr>
<td>Neurological, permanent</td>
<td>50</td>
<td>3</td>
<td>6.0%</td>
</tr>
<tr>
<td>Sympathetic disturbance</td>
<td>65</td>
<td>12</td>
<td>18.5%</td>
</tr>
<tr>
<td>Scar pain or numbness</td>
<td>50</td>
<td>5</td>
<td>10.0%</td>
</tr>
<tr>
<td>Hematoma</td>
<td>50</td>
<td>12</td>
<td>24.0%</td>
</tr>
<tr>
<td>Visceral dysfunction</td>
<td>50</td>
<td>1</td>
<td>2.0%</td>
</tr>
<tr>
<td>Retroperitoneal hematoma</td>
<td>50</td>
<td>1</td>
<td>2.0%</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>50</td>
<td>1</td>
<td>2.0%</td>
</tr>
<tr>
<td>Increased pain</td>
<td>50</td>
<td>5</td>
<td>10.0%</td>
</tr>
<tr>
<td>Micturition disturbance</td>
<td>50</td>
<td>1</td>
<td>2.0%</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>50</td>
<td>4</td>
<td>8.0%</td>
</tr>
<tr>
<td>Retrograde ejaculation</td>
<td>93</td>
<td>2</td>
<td>2.2%</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>50</td>
<td>1</td>
<td>2.0%</td>
</tr>
<tr>
<td>Phlebitis</td>
<td>105</td>
<td>2</td>
<td>1.9%</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>105</td>
<td>2</td>
<td>1.9%</td>
</tr>
<tr>
<td>Acute leg ischemia</td>
<td>105</td>
<td>1</td>
<td>0.9%</td>
</tr>
<tr>
<td>Infection of prosthesis</td>
<td>50</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Taken together, these results, albeit based on sparse data, suggest that the risks associated with the SBC device are primarily those of surgery on the spine, whether for IVP placement or spinal fusion.

However, an additional issue for any IVP device is the rate of complications related to placement of the device. Distinct from device failure, these complications typically necessitate reoperation relatively soon after device placement. In the English language literature, reports of such complications to date have been limited, reflecting the market reality that the single largest market for the SBC has been Germany. Thus, the published English language reports likely represent a reasonable estimate of the upper bound of the rates of such events, since they are drawn from the early experience with the device. A meeting presentation regarding a series of 96 patients reported 10 reoperations, (10.4%), eight of which were for spinal fusion due to complications of device placement. (12) A published paper reporting 2 year follow-up of the first 50 patients from a single centre in the Netherlands noted that 12 (24%) underwent reoperation, 6 of which were at the same level as the IVP device. Two of these six were for spinal fusion. (13) By comparison, reoperation rates for interbody fusion cages are reported to range from 1.3% to 29%, although some unspecified proportion of these reoperations were in response to failed fusion rather than
an immediate post-operative complication associated with the cage device. Overall, rates of reoperation for the SB Charite artificial disc appear broadly consistent with rates for interbody fusion devices.

**Bryan Cervical Disc (BCD)**

The BCD device is used for IVP in the cervical spine. Device placement is reported to be complex, in part due to the exacting preparations needed to locate the device correctly. Published data on the BCD device are sparser than for the SBC device.

In the published literature, a series of seven patients from Australia reported no intraoperative or postoperative complications. Three of seven had at least six months of follow-up and no reoperations were reported. (14) A larger series of 97 patients treated at European centres identified 3 reoperations – one for evacuation of a hematoma and one for insertion of the device at the wrong level. The other reoperation was described as a posterior foraminotomy unrelated to the BCD device in response to a patient’s complaints of pain at follow-up. No device failures had occurred among the 60 patients in whom at least six months of follow-up had been completed. (15)

**ProDisc II (PD2)**

The PD2 device was developed by a French surgeon for lumbar spine IVP. He has presented 7-11 year follow-up data on 58 of the 64 patients in his original series. Among this group, 5 complications were reported: retrograde ejaculation (2), unspecified ‘uneventful’ vascular problems (2), and hematoma & wound infection (1). No device failures were reported. (13) These data are cited in several publications as personal data of or presentations by the inventor (3,11,12,16) and were published in a supplement to a peer-reviewed publication. (17)

As with complications of other IVP devices, published small-scale series suggest generally low rates of events primarily associated with surgical access. A series of 34 patients followed for an average of 5.8 months reported three complications: one case of retrograde ejaculation, one reoperation due to incomplete device fixation, and one nerve root irritation due to compression by nucleus material. (18) A larger series of 134 PD2 insertions in 108 patients reported one complication, a case of postoperative septicemia that the authors state was unrelated to the PD2 device. (19)

The PD2 device is currently being assessed for FDA approval in the United States via a randomized controlled trial under an investigational device exemption (IDE). The study is randomizing participants with lumbar DDD to PD2 or spinal fusion in a ratio of 2:1. Two of the participating centres have reported preliminary data on patients treated in a single centre. The smaller of the series reported one superficial wound infection and one device dislodgement requiring reoperation among 28 recipients of PD2. In addition, one patient complained of sacroiliac joint pain and two of right leg pain. (17) The larger series reported that no reoperations or device failures occurred among 35 PD2 recipients. (20)

In summary, all three IVP devices carry risks associated with alternative approaches to surgical management of DDD. Reported re-operation rates vary widely, but sparse data and varying durations of follow-up suggest that comparisons among them would be imprudent at this time (Table 3).
Table 3: Re-operation rates for devices used to surgically treat degenerative disc disease

<table>
<thead>
<tr>
<th>Device</th>
<th>Reoperation Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lumbar interbody fusion cage</td>
<td>1.3 - 29%</td>
</tr>
<tr>
<td>SB Charite III</td>
<td>10.4 - 24%</td>
</tr>
<tr>
<td>Bryan Cervical Disc</td>
<td>3.1%*</td>
</tr>
<tr>
<td>ProDisc II</td>
<td>3.0%*</td>
</tr>
</tbody>
</table>

*: insufficient data for accurate estimates (fewer than 100 cases each)

Nucleus Replacement Devices

Nucleus replacement devices (NRD) are a more recent development than IVP devices. As a result, the available data on both safety and effectiveness are more sparse than for IVP. The largest human experience reported to date has been for the PDN device. No other NRD was identified for which significant human experience has been reported.

Prosthetic Disc Nucleus (PDN)

This device has been approved for use in Europe and a number of countries in Asia. Published experience with the device is however, limited. A series of 46 patients reported 4 cases of device extrusion requiring reoperation and one surgical infection. (21) A series of 45 patients, of whom follow-up data were available on only 30 reported that ‘implant migration’ was found in 8/30 patients. None had back pain or nerve root compression symptoms and none underwent reoperation. (22)

Movement of the device was also reported in 3 of 8 patients from a series reporting an anterolateral transpsoatic approach, (23) but the clinical significance of this relatively high rate of movement or migration will likely require longer follow-up of greater numbers of patients. Non-human testing has, to date, reported no wear debris from the PDN device. (24)

Clinical Outcomes

Overall, surgery for DDD remains a technique about which there is little consensus. A Cochrane review of studies published through December 31, 1999 identified 16 randomized or quasi-randomized trials and concluded ‘there is no scientific evidence about the effectiveness of any form of surgical decompression or fusion for degenerative lumbar spondylosis compared with natural history, placebo, or conservative treatment. (25)

Since that review, investigators leading a reasonably well-designed Swedish study concluded that lumbar fusion by any of three techniques (posterolateral fusion, posterolateral fusion with internal screw fixation, and posterolateral fusion with internal screw fixation and interbody fusion) yielded statistically significant reductions in patient-reported back pain and disability compared to conservative treatment consisting of physiotherapy. Results among the various surgical groups did not differ significantly, suggesting that no particular approach was superior. (26) In addition, social insurance records were used to assess work disability and the ‘net back to work rate’ was 36% among surgical patients compared to 13% among the non-surgical patients. (27) Even in this study, however, the authors stress the importance of careful
selection of patients for surgery, a view that is widespread in the literature on surgical management of DDD.

To assess artificial disc devices, the relevant question is one of demonstrating, at a minimum, the equivalence of outcomes among patients implanted with the device in question to outcomes among patients undergoing spinal fusion surgery. For policy purposes, any relative improvement of outcome for an artificial disc device over prevailing practice is important as an input to comparing cost-effectiveness of the various approaches to surgical management of DDD. In addition, differences in resource use (e.g. operating room time, duration of post-operative hospital stay) for different approaches to spinal surgery are expected to be significant although the literature demonstrating these differences is dwarfed by that asserting that such differences are to be expected.

Following the format of the Medical Advisory Secretariat, Table 4 summarizes the provenance of the literature describing studies of effectiveness of artificial disc devices for surgical management of DDD.

### Table 4: Level of evidence of literature focussing on effectiveness of artificial disc devices for surgical management of DDD, November 2003

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Study Design</th>
<th>Number of Eligible Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Large randomized controlled trial, systematic reviews of RCTs</td>
<td></td>
</tr>
<tr>
<td>1(g)</td>
<td>Large randomized controlled trial unpublished but reported to an international scientific meeting</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Small randomized controlled trial</td>
<td>3</td>
</tr>
<tr>
<td>2(g)</td>
<td>Small randomized controlled trial unpublished but reported to an international scientific meeting</td>
<td></td>
</tr>
<tr>
<td>3a</td>
<td>Nonrandomized study with contemporaneous controls</td>
<td></td>
</tr>
<tr>
<td>3b</td>
<td>Nonrandomized study with historical controls</td>
<td></td>
</tr>
<tr>
<td>3(g)</td>
<td>Nonrandomized study presented at international conference</td>
<td></td>
</tr>
<tr>
<td>4a</td>
<td>Surveillance (database or register)</td>
<td></td>
</tr>
<tr>
<td>4b</td>
<td>Case series (multi-site)</td>
<td>6</td>
</tr>
<tr>
<td>4c</td>
<td>Case series (single site)</td>
<td></td>
</tr>
<tr>
<td>4d</td>
<td>Retrospective review, modelling</td>
<td></td>
</tr>
<tr>
<td>4(g)</td>
<td>Case series presented at international conference</td>
<td></td>
</tr>
</tbody>
</table>

Tables 5, 6 and 7 summarize the results of these 9 studies. Outcomes have been classified as radiologic (typically assessed by the presence of fusion on computerized tomography (CT) images), patient (pain, disability), and health system & societal (length of stay, rehabilitation costs, return to work). Tables are organized by anatomic site (cervical, lumbar) and type of study (randomized, non-randomized but comparative, case series).
Table 5: Summary of literature on artificial discs for cervical spine surgical treatment of degenerative disc disease, to November 2003

<table>
<thead>
<tr>
<th></th>
<th>RCT</th>
<th>Non-randomized comparative</th>
<th>Case series</th>
<th>Case series</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device</strong></td>
<td>No trials identified</td>
<td>No studies identified</td>
<td>Ryan Cervial Disc @ C3-C4, C4-C5, C5-C6 or C6-C7 levels (14)</td>
<td>Bryan Cervical Disc @ C3-C4, C4-C5, C5-C6 or C6-C7 levels (15)</td>
</tr>
<tr>
<td><strong>Number of subjects for device</strong></td>
<td>7</td>
<td>60</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Control device</strong></td>
<td>Not applicable</td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number of subjects for control device</strong></td>
<td>Not applicable</td>
<td>Not applicable</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Outcomes:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Radiologic outcomes</strong></td>
<td></td>
<td></td>
<td>-Some degree of correction of lordosis loss in 2/7 -9/9 had 'good' range of cervical motion on fluoroscopy</td>
<td>-Data available on 57/60 patients at 6 months and 24/30 at 1 year -At 6 months, the Cobb angles indicating non-fusion, 4/57 were unable to be interpreted -At 12 months, 21/24 had non-fusion, 1/24 had fusion and 2/24 were unable to be interpreted</td>
</tr>
<tr>
<td><strong>Patient Outcomes</strong></td>
<td></td>
<td></td>
<td>-Nurick grade improved 0.72 (p&lt;0.5) -Oswestry Neck Score improved average of 51.4 points (p&lt;0.05)</td>
<td>-At 6 months, 41/57 'excellent' by Odom’s criteria -At 12 months, 24/27 ‘excellent’ -Post-operative mean SF-36 score met of exceeded that of United States population -Pre-operative to post-operative SF-36 comparison appears not to be significantly improved</td>
</tr>
<tr>
<td><strong>Health system and societal outcomes</strong></td>
<td>Not reported</td>
<td></td>
<td></td>
<td>-Mean hospital stay=3.6 days (1-10 days range)</td>
</tr>
</tbody>
</table>
Table 6: Summary of randomized controlled trial (RCT) literature on artificial discs for lumbar spine surgical treatment of degenerative disc disease, to November 2003

<table>
<thead>
<tr>
<th>Device</th>
<th>SB Charite III Lumbar IVP (23;29)</th>
<th>ProDisc II (17)</th>
<th>ProDisc II (20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects for device</td>
<td>41</td>
<td>28</td>
<td>35</td>
</tr>
<tr>
<td>Control device</td>
<td>BAK interbody autograft fusion</td>
<td>Interbody autograft fusion</td>
<td>Interbody autograft fusion</td>
</tr>
<tr>
<td>Number of subjects for control device</td>
<td>19</td>
<td>11</td>
<td>18</td>
</tr>
<tr>
<td>Outcomes:</td>
<td>- Aggregate results combining all 60 patients reported. Comparison to a Japanese series of 62 surgical decompressions for spinal stenosis (not DDD) provided as evidence of equivalent improvement with either artificial disc or control device.</td>
<td>-Significantly greater L4-L5 motion for ProDisc II patients compare to fusion patients</td>
<td></td>
</tr>
<tr>
<td>Radiologic outcomes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient Outcomes</td>
<td>-At 6 months, Oswestry scores improved from about 63 to 34 among ProDisc patients compared to change from 60 to 44 among fusion recipients (p&lt;0.05)</td>
<td>-ProDisc II patients had lower Oswestry scores at 3 months than fusion patients but similar scores at 6 months</td>
<td></td>
</tr>
<tr>
<td>Health system and societal outcomes</td>
<td>-ProDisc II patients had shorter operating room times than fusion patients (75 vs 218 minutes) and shorter hospital stays (2.1 vs 3.5 days (p&lt;0.05)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 7: Summary of case series studies on artificial discs for lumbar spine surgical treatment of degenerative disc disease, to November 2003

<table>
<thead>
<tr>
<th>Device</th>
<th>SB Charite III Lumbar IVP (30)</th>
<th>SB Charite III Lumbar IVP (30)</th>
<th>SB Charite III Lumbar IVP (30)</th>
<th>ProDisc II at L4-L5 or L5-S1 levels (33)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of subjects for device</td>
<td>41</td>
<td>50</td>
<td>57</td>
<td>33</td>
</tr>
<tr>
<td>Radiologic outcomes</td>
<td>-At 2 years, 28/38 patients had ‘good’ technical results radiographically</td>
<td></td>
<td></td>
<td>-Among L4-L5 recipients, mean range of motion was 10 degrees (range 8-18) and among L5-S1 recipients, mean range of motion was 8 degrees (range 2-12)</td>
</tr>
<tr>
<td>Patient Outcomes</td>
<td>-At 3 years, ODS changed from 52.2 to 33.4 (p&lt;0.05)</td>
<td>-At 2 years, 30/46 patients reported less pain than they had preoperatively</td>
<td>-At 12 months, Oswestry scores improved (p&lt;0.05)</td>
<td>-At 12 months, Oswestry scores improved from 56 to 18 (p&lt;0.05)</td>
</tr>
<tr>
<td>Health system and societal outcomes</td>
<td>-Mean hospital stay=10 days; 35/43 patients returned to some work, 43% to original work</td>
<td></td>
<td></td>
<td>-Mean operating room time=78.7 minutes, 95.2 for L4-L5 level and 74.4 for L5-S1 level</td>
</tr>
</tbody>
</table>

Summary of Medical Advisory Secretariat Review

- IVP products have been widely used in Europe and Asia. Safety data suggest that events are primarily those associated with any surgery to the spine. Based on the limited reports in the literature, neither IVP device failure or debris production are likely to occur.

- NRD products are newer, target less severe disease, and have not been sufficiently evaluated to draw any conclusions regarding safety or efficacy. These technologies should be reviewed at least annually as several products are in various stages of pre marketing investigation.

- The choice of IVP rather than spinal fusion reflects a significant conceptual and philosophical divide among spine surgeons. Comparative efficacy data for IVP and spinal fusion are at present sparse, but are expected within the coming 12-24 months for all three IVP products reviewed here: SB Charite III, Bryan Cervical Disc and ProDisc II.

- Based on preliminary analyses of single centre data from the IDE trial of the ProDisc II product, this IVP appears to yield more rapid postoperative recovery of function than fusion and lower postoperative disability scores than fusion. The multi centre IDE trial will provide data on outcomes at two years.

- The randomized trials for both the SBC and PD2 product have excluded people greater than 90 kg or with high body mass index (BMI). IVP devices may perform less well in heavier patients due to the...
increased axial loading of greater body mass. Assessing the role of IVP in spinal surgery would ideally include an analysis of current case loads and surgical approaches categorized by patient weight.

Economic Analysis

Given the absence of large-scale RCTs to establish an effectiveness advantage in favour of artificial disc devices, the small-scale trials in the literature suggest an equivalence of IVP devices with spinal fusion using interbody cage devices and autologous bone. As with the INFUSE™ device, (see accompanying review), one of the challenges in economic analysis is trading off patient preferences for avoiding the pain of the iliac crest bone harvest against the cost of the device.

At this time, the availability of IVP devices does not appear to expand the spectrum of indications, nor free up substantial resources for increasing surgical case volumes. Contrary to the United States where surplus hospital bed and operating room capacity, coupled with relatively generous Medicare reimbursement for persons over 65 and a higher ratio of neurosurgeons to population appear to be driving rates of surgery, the Canadian context does not have appreciable amounts of hospital or operating room capacity available.

Should NRD devices be approved for marketing in Canada, demand and case volumes may well increase due to a confluence of several factors, including indicated use for less severe DDD (of whom there are likely to be greater numbers of persons, particularly as magnetic resonance imaging continues to diffuse) and the potential for outpatient implantation or at least less resource-intensive surgical procedures.

At this time, given these devices’ relatively low sales in Canada, price data are likely to overstate costs, since volume purchasing would be expected to lower per-device costs. In addition, differences in surgical approaches, both among the various devices and also in comparison to spinal fusion are likely to have cost implications. Based on the very limited evidence available at this time, it is not possible to state whether these are cost savings or cost increases.

In summary, definitive evidence of a per-procedure cost increment or savings over current approaches to spinal fusion is not available. Data on negotiated device prices could be a useful input to a cost-effectiveness analysis, ideally to be completed within the context of a broader review of surgical management of DDD.
ARTIFICIAL DISCS

References


