Lumbar disc arthroplasty – where are we at present?

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Abstract

The combination of a high incidence of low back pain in the general population and commercial pressure has led to a proliferation in spinal implants and the incidence of spinal surgery. Fusion surgery has been the mainstay, but more recently there is a drive to maintain spinal mobility with the use of dynamic implants, notably the lumbar disc replacement. It is rapidly being accepted by many without the necessary scientific backing.

This review looks at the available literature as far as the requirements of such an implant, and the currently available clinical results.

Despite some encouraging clinical outcomes, lumbar arthroplasty must still be considered experimental, and the suggested long-term benefits still need to be proved. It is important that the enthusiasts collect their outcomes data so that the true role of these devices can be established.

Introduction

Low back pain is an ever-present problem with 80% of the population experiencing this symptom in their lifetime. This creates a huge financial burden to society. An epidemiological study in Australia reported that in 2001, in a six-month period 10% of adults suffered from severe low back pain. The direct cost for 2001 in Australia was 1.05 million Australian dollars, and when the indirect costs such as loss of productivity were added, this rose to 8.15 billion Australian dollars (presented at the Australian Spinal Society meeting 2003).

Along with the high incidence of low back pain is the commercial pressure to develop a market for their products. This is evidenced by the proliferation of various treatment modalities and surgical implants. An example of this is a 215-page document published by one of the international merchant banks entitled Spine arthroplasty: market potential and technology update. This extensive text states that the "spine implant market could become a multi-billion dollar market in the new millennium", and predicts a 25-35% compounded annualised growth, with arthroplasty being 33% of the lumbar spinal market by 2010.1

With the surgical enthusiasm of many colleagues and commercial pressure, it becomes difficult but more important to look carefully at true role of lumbar arthroplasty.

The disc as the pain source

The spine is a three joint complex with multiple potential sources of pain, viz. annulus, endplates, facet joints, facet capsules and posterior ligaments. The intervertebral disc has been identified as a common source of pain.2 Nociceptor fibres, containing neurotransmitters such as substance P and transmitting via the sinuvertebral nerve have been identified in the PLL, the posterior disc annulus and even the nucleous pulposus in diseased discs.3-5 These nociceptor fibres are stimulated by annulus tears or by stretching of mechanoreceptors. Various chemical mediators such as phospholipase A2, prostaglandin E and polypeptide amines may increase nociceptor sensitivity. Low back pain has been correlated with disc space and vertebral end-plate changes on MRI of the spine.6 Concordant pain and radiological evidence of internal disc disruption has been produced on discography of LBP patients.7-11 All of the above findings have led to the concept of discogenic back pain.
The primary treatment of discogenic back pain includes analgesic and anti-inflammatory medication, weight loss, behaviour and lifestyle modification, physical therapy, including abdominal stabiliser strengthening, cessation of smoking and orthotic supports. Many patients respond to these treatments over a period of 2-6 weeks. There is, however, a group that does not respond to conventional, conservative therapy. These patients go on to have chronic, debilitating low back pain and may be candidates for surgical treatment.

The case for arthroplasty

Traditional surgical methods for discogenic low back pain aim to fuse a motion segment, minimising shear forces across a disc space and reducing stimulus of nociceptor fibres. Fusion may also restore disc height and spinal alignment, thereby restoring the length over which spinal muscles act. Other secondary aims of surgery may be to denervate the facet joints and excise the disc itself.

Currently arthrodesis is the gold standard for axial back pain in a well-selected patient group. This in itself is a problem as the selection criteria vary and the application thereof is different by different surgeons. Despite fusion surgery being widely practised, it is not well substantiated by scientific data. This is largely due to many small series, which are often observational rather than tight scientific studies. A review by Bono15 looked at the last 20 years of literature reports on lumbar fusion. He reports on the poor quality of papers, with half not providing clear methodology. Overall he reports an 87% fusion rate, with good to excellent results in 79%.

It with this background that arthroplasty must be compared. The failure of fusion, some poor results in 20% or so, and late sequelae have motivated surgeons to look towards a mobile solution. Ethni13 stated 20 years ago that “fusion generates a conflict between immediate benefit and late consequences”. This view is still held by many, and largely due to the clinical experience of supra-jacent disc breakdown.

This concept of breakdown itself is not resolved. Degenerative changes affect multiple levels, and may progress irrespective of whether an adjacent segment is fused or not. There are proponents that categorically state supra-jacent breakdown is inevitable, yet Gillett14 reviews the literature regarding this and concludes that the knowledge of the fate of transitional segments after lumbar fusion remains largely incomplete. His personal series of 106 patients had adjacent segment changes in 38%, with his single level fusion requiring re-operation in 11%. Fraser15,16 reported on interbody lumbar fusions at 20 years, and found only 8.4% required re-operation.

The potential advantages of total disc replacement are the maintenance of motion, the avoidance of pseudoarthrosis and avoidance of juxta-articular degeneration. This is met by the potential disadvantages of implant failure, host reaction to debris and long-term facet degeneration and pain.

The ideal intervertebral disc replacement

Hedman17 defined the required design criteria of intervertebral disc replacement, viz. endurance, materials, geometry, kinematics, dynamics, constraint, fixation to bone and the need to be fail-safe.

Endurance

Hedman17 stated that due to the risks of anterior revision surgery, the disc prosthesis should last the life of the patient. This is an extreme challenge, as our current well-established arthroplasty technologies for hip and knee cannot achieve this despite years of development. Due to the envisaged use in young patients the expected lifespan of a disc prosthesis is up to 40 years. Hedman conservatively estimated an anticipated 85 million spinal loading cycles. This is close to 10 times longer than reported wear tests on orthopaedic implants at that time.

Materials

The volume of wear particles is a concern and it is necessary to keep this to a minimum. It is well established that wear particles cause a local inflammatory response, and with the neurological and vascular structures nearby, the result could be catastrophic. The choice of ultra high molecular weight polyethylene is important. McAfee18 explains that the Charite uses compression-moulded sheet polyethylene that is gamma-irradiated as opposed to highly cross-linked, because although the cross-linked has a reported lower osteolysis rate, it has higher deformation characteristics and therefore greater chance of deformation and fracture. The calculated wear rate of the Charite UHMWP is less than 0.152 mm/year. Despite the reintroduction of a metal-on-metal prosthesis, there are still concerns due to increased systemic distribution of small particle wear debris, with a 0.5% incidence of hypersensitivity.

Geometry

Hedman17 stated that the device should be contained within the disc space. Failures by subsidence have been seen due to small implants, and it is important that there is peripheral loading to prevent endplate fracture.

Kinematics and constraint

It is accepted that the instantaneous axis of rotation (IAR) in flexion/extension of the normal lumbar varies for levels and migrates during motion. In general it is posterior to the midline and slightly below the endplate of the inferior vertebrae. At the L5/S1 level the IAR is within the disc space. During motion this IAR moves in an elliptical fashion. The Charite group believe that this is nearly reproduced with their device (McAfee18).
They state that this posterior migration of the IAR with flexion is only possible without impingement, with a mobile core between endplates, i.e. their design.

This is important when looking at the design of the available prosthesis. The issue of constraint is well dealt with by Huang.\textsuperscript{19} He states that total disc replacement requires little or no restraint to rotation, and therefore can define constraint as the limitation of pure antero-posterior or lateral translational intervertebral motion.

Of the available prostheses he uses the ball and socket design of the Prodisc as an example of constraint. The ball and socket have the same radius of curvature, and this makes pure translation of cephalad body impossible. Apparent translation occurs by rotation of the vertebral body around the implant’s IAR.

By contrast, the Charite is unconstrained. It has two concave endplates with a biconvex disc interposed. This spacer is free to rotate, and therefore pure antero-posterior and lateral translation of the cephalad vertebrae is permitted.

Both extremes of constraint cause failure, with high constraint causing implant loosening and low constraint resulting in dislocation.

He also comments on the Prodisc IAR being below the inferior endplate, whereas the Charite is in the disc. Unconstrained designs have the advantage kinematically to be more likely to provide a physiological mobile IAR and therefore greater range of motion \textit{in vivo}. The ability to translate may reduce facet and posterior ligamentous loads and is more forgiving in terms of motion for misplacement. The constrained model protects shear loading of the posterior elements.

\section*{Dynamics}

The physiological transmission of load to the adjacent segments is important. Too little will result in resorption of bone and too much will cause supra-jacent degeneration.

\section*{Fixation to bone}

Screws and press-fit components (spikes, etc) only provide early fixation, whereas porous coating needs six weeks to become stable. Some of the newer designs incorporate both these features to facilitate early and long-term stability.

\section*{Fail-safe}

It is important that, in the event of prosthesis failure, it does not cause catastrophic events.

\section*{Results}

There are two main players at present, Charite and Prodisc (\textit{Figures 1-3}) with a more recent addition of a metal-on-metal design, the Maverick (\textit{Figure 4}). We have a local design in SA.

The Charite has been around the longest, but unfortunately there are frequent design changes which make result interpretation difficult. Griffith \textit{et al}\textsuperscript{20} reported on the European Experience in 1994. This multicentre retrospective review analysed 139 Model 3 prostheses in 93 patients. The follow-up was short at an average of 11.9 months. There was improved back pain in 65%.
Enker reported on the Acroflex disc replacement in six patients, with four satisfactory results at 3.4 years. This prosthesis has subsequently been withdrawn from the market due to hardware failure.

Cinotti reported on 46 patients with the Charite disc. There were 63% satisfactory results. Vertebral motion average 9°, with a supra-jacent motion of 16°.

Lemaire reported on a large series of 105 cases with a mean follow-up of 51 months. There was improvement in back pain in 90.5%. Eighty-seven per cent of patients returned to work, which is impressive as 50% of the cohort were manual labourers.

Mayer et al reports on 34 patients where he implanted a Prodisc via a minimally invasive technique. The average follow-up was only 5.8 months. Seventy-six per cent had no back pain at follow-up. The patients’ hospital stay was an average of 12 days.

McAfee et al reports on 41 Charite discs in a prospective randomised trial, where they are compared against stand-alone BAK cages. Although stand-alone cages are probably not the best choice of fusion, it is at least a prospective randomised trial. All were well selected with MRI and provocative discography, and had failed an extensive six-month conservative programme. Their Charite group improved in VAS from 73.5 to 30.4 and Oswestry from 50 to 25.

Zigler et al reported on six-month results of a prospective randomised study where Prodisc II and a 360° fusion were compared. The Prodisc procedure was shorter in duration, and the patients were discharged earlier.

Bertagnoli et al reported on 134 Prodisc II prostheses in 108 patients. He claims 98% good and excellent results, but only 54 patients had follow-up for more than a year. It is unclear how long the actual follow-up was.

Kim et al present an almost five-year follow-up of 11 cases where disc replacements were used to treat supra-jacent disc degeneration above an established fusion. This is important as this problem is only exacerbated by extension of the fusion. They report a reduction in the patients’ Oswestry score from 64% to 24%.

Putzier reported a 17-year follow-up of 52 patients in which 63 Charite prostheses had been implanted. These included all three versions of the Charite. Only 23 patients had good or excellent outcome, the majority of whom had undergone spontaneous ankylosis, i.e. achieving a fusion rather ongoing mobility as intended.

Complications
When reviewing the complications in the aforementioned papers, they are made out to be unrelated to the arthroplasty or of low magnitude. Their incidence is variable, but tends to be between 5-10%. They are related to the anterior approach, with vascular events, or more implant-related with migration, subsidence or iatrogenic stenosis and root pain. There is of course failure to free patients of their back or leg pain, but this is not attributed to the procedure.

Mayer reports a 7.8% complication rate in a small series, with root pain from disc extrusion into the foramen. There was also a tray dislocation anteriorly.
Lemaire reported 5% vascular problems with two pulmonary emboli, and one leg ischaemia. There were two endplate fractures, and a transient L5 palsy. Griffith reported a 6.5% incidence of prosthesis migration or dislocation. There has been one death reported due to small bowel obstruction felt to be due to the retraction during the anterior exposure.

Despite this low reported incidence of significant complications, Ooij et al write an interesting paper on 27 cases who presented with back and/or leg pain following disc arthroplasty done in a nearby unit. These presented on average 53 months following arthroplasty surgery. Four of the cases required removal of the prosthesis, and 11 cases secondary reconstructive surgery. They attributed the cause of pain to subsidence and facet osteoarthritis. Ooij comments on Hedman’s list of design requirements and states “[it] appears almost impossible to manufacture a disc prosthesis that possesses all the characteristics”. They performed posterior instrumented fusions as a salvage procedure, but were disappointed with the results. It therefore does not appear as simple as doing the fusion if the arthroplasty fails, as advocated by many.

**Table I: SA Spinal Society guidelines**

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<th>Indications</th>
<th>Contraindications</th>
<th>Other requirements</th>
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<tbody>
<tr>
<td>Age less than 50 years old</td>
<td>Osteoporosis</td>
<td>At least three months active, managed, conservative care</td>
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<td>Origin of pain proven to be from the degenerative disc</td>
<td>Listhesis</td>
<td>Patient informed that the procedure is new and long term effects are unknown</td>
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<td>Normal or near normal facet joints</td>
<td>Abnormal facet joints</td>
<td>Patient informed that the complications are not easily reversed</td>
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<td>Preferably single level</td>
<td>Fractures</td>
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<td></td>
<td>Infection</td>
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<td>Tumours</td>
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<td>Radicular pain</td>
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<td></td>
<td>Spinal stenosis</td>
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<td>Non-contained herniated disc</td>
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<td></td>
<td>Scoliosis</td>
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<td>Morbid obesity</td>
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<td>Arachnoiditis</td>
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<td>Vascular pathology</td>
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<td>Less than 5 mm disc height</td>
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We have not yet found the answer to eradicating degenerative axial pain. Although arthrodesis falls short of this, it provides a significant symptomatic improvement in most patients if well selected. While the theoretical advantages may appear attractive, we must not allow our dissatisfaction with one procedure to permit the blind acceptance of another, which is generally more aggressive and less predictable in terms of long-term outcome. As highlighted by Kleuver’s meta-analysis of the available literature, despite implantation of disc replacement devices for more than 10 years, there is no strong evidence that arthroplasty is any better than fusion surgery. Only recently have randomised prospective studies been commenced, although the choice of fusion control may already reduce their value.

Due to the unknown long-term performance of these devices, they should be used with caution. They should be regarded as experimental in nature and all recipients should be made aware of this, as well as the potential risks should they fail and require removal or secondary surgery.

For the enthusiasts that implant these devices, accurate and ongoing data should be kept to facilitate our learning for their role in the future.

The SA Spine Society has made a set of guidelines available as listed in Table I. It has also facilitated a database to collect prospective data on lumbar arthroplasty, and all surgeons are urged to contribute their data so that the true role of lumbar arthroplasty can be established.

**References**


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