Cervical spinal disc replacement is used in the management of degenerative cervical disc disease in an attempt to preserve cervical spinal movement and to prevent adjacent disc overloading and subsequent degeneration. A large number of patients have undergone cervical spinal disc replacement, but the effectiveness of these implants is still uncertain. In most instances, degenerative change at adjacent levels represents the physiological progression of the natural history of the arthritic disc, and is unrelated to the surgeon. Complications of cervical disc replacement include loss of movement from periprosthetic ankylosis and ossification, neurological deficit, loosening and failure of the device, and worsening of any cervical kyphosis. Strict selection criteria and adherence to scientific evidence are necessary. Only prospective, randomised clinical trials with long-term follow-up will establish any real advantage of cervical spinal disc replacement over fusion.

Intersegmental fusion is the accepted method of treating segmental deformity, instability and painful degenerative disease of the cervical spine after all reasonable non-operative measures have failed. A number of studies with follow-up of more than 30 years have been published. Recently, several techniques which do not involve fusion have been developed for the management of degenerative intervertebral disc disease in the younger adult population. This is a group of patients whose characteristics differ markedly from those who require other joint replacements. Cervical disc replacement aims to preserve the movement of the affected segment and to prevent overload of the adjacent discs and subsequent degeneration. It has been estimated that 43% of those who require surgery for degenerative conditions of the cervical spine would meet the current criteria for cervical disc replacement.

Implants

The implants used for cervical disc replacement can be classified on the basis of materials, design, type of fixation, and kinematics. They can also be non-, uni- or bi-articular. Metal-on-metal, metal-on-polymer (ultra-high molecular-weight polyethylene), ceramic-on-polymer, and ceramic-on-ceramic devices have been implanted. They may be modular or not. Some require vertebral body screw fixation, others are press-fitted. They may be constrained, semiconstrained or unconstrained.

To date, several types have been implanted in man, but consistent data on their clinical results have been reported only for a few: the Bryan Cervical Disc (Medtronic Sofamor Danek, Inc., Memphis, Tennessee) (Fig. 1) the Prestige (Medtronic Sofamor Danek) (Fig. 2) and the Prodisc-C (Synthes-Spine, Paoli, Pennsylvania) (Fig. 3).

The Bryan Cervical Disc (Fig. 1) has the longest clinical and radiological follow-up. It is a metal and polyurethane implant, with characteristics of movement and shock absorption which are similar to those of the intact disc. It consists of two titanium alloy shells which contain a polyurethane nucleus. The shells are fixed to bone by a porous titanium layer and the device is enclosed by a flexible polyurethane membrane giving a closed articular space.

The first prospective, multicentre clinical trial of the Bryan cervical disc replacement for single-level degenerative disease was published in 2002. However, only 30 of the 97 recruited patients were available for follow-up after one year and, of these, only 24 had full clinical and radiological data available. Some movement was preserved after one year in 21 patients (87.5%). Any complications were related to the surgical technique and to migration of the device. In a further paper with a longer follow-up and using implants at two levels, similar results were obtained. Movement was preserved in
79 of the 90 patients (87.8%) with a single-level implant, and in 42 of the 49 (85.7%) with two-level implants, with good clinical results.6

In another study in 14 patients, the Bryan cervical disc showed preservation of the range of movement (ROM) at the replaced levels at follow-up at two years.7 The shell angle, which measures the angle of disc space,7 became kyphotic after surgery (mean change -8.2°), resulting in segmental kyphosis, although the Cobb angle from C2-7, which measures spinal alignment in the sagittal plane,8 was preserved. There was also an increase in the overall range of cervical spinal movement from an increase in movement of the adjacent discs.

More recently, the Bryan cervical disc replacement has been implanted in patients with myelopathy. Lafuente et al9 reported the overall clinical results in 46 patients with radiculopathy or myelopathy who required discectomy for cervical spondylolisthesis. Nine patients had myelopathy, of whom three had already undergone cervical fusion at a single level. The remaining 37 patients had radicular symptoms. The reported complications included temporary worsening of muscle spasms in one patient, a mild transient postoperative dysphonia in three, bony ankylosis in two, and revision for loosening after a fall in one. The results were better in patients with radiculopathy than in those with myelopathy.9 Patients with a radiculopathy had a greater chance of returning to normal, whereas those with myelopathy were more likely to experience residual symptoms.

In a different two-year multicentre, randomised trial comparing cervical disc replacement (n = 17) with anterior cervical discectomy and fusion (n = 16) in patients with radiculopathy or myelopathy, the implant maintained the segmental range of movement, and the clinical results were similar to those achieved with fusion.10 Recently, a prospective study of 115 patients with single-level cervical disc disease randomised to a Bryan cervical disc replacement (56 patients) or to an anterior cervical discectomy and fusion with allograft and plate (59 patients) it was found that the cervical disc replacement group compared favourably with the discectomy and fusion group at a follow-up of one to two years.11 Each patient suffered from radiculopathy or ‘focal’ myelopathy. None had the diffuse retrovertebral compression which occurs with ossification of the posterior longitudinal ligament. There were significant differences between the two groups at follow-up at two years with a statistically better outcome for neck and arm pain in those in the disc replacement group in the Neck Disability Index (NDI),12 a visual analogue score, and the SF-36 physical component score.13 Moreover, fewer re-operations

Fig. 1
Photograph showing the Bryan Cervical Disc (Medtronic Sofamor Danek Inc., Memphis, Tennessee).

Fig. 2
Photograph showing the Prestige LP implant (Medtronic Sofamor Danek Inc., Memphis, Tennessee).

Fig. 3
Photograph showing the Prodisc-C (Synthes-Spine, Paoli, Pennsylvania).
were needed in the cervical disc replacement group (2 vs 4). Of the four patients in the discectomy and fusion group, two had symptomatic nonunion; one subsequently needed posterior cervical fusion and the other revision anterior cervical discectomy and fusion with Recombinant human BMP-2 (rhBMP-2) and plating. Two patients in the fusion group required fusion at an adjacent level. The two re-operations in the disc replacement group were both anterior discectomy and fusion for adjacent-level disease.

A recent multicentre study reported 463 patients randomised to Bryan cervical disc replacement (n = 242) or anterior discectomy and fusion with allograft and plating (n = 221) of whom 424 were available for follow-up at 24 months. Fusion had occurred in 208 (94.1%) of the anterior discectomy and fusion group. Overall success (based on 15-point improvement in NDI score, maintenance or improvement in neurological status, no serious adverse reaction related to the implant or surgical procedure and no subsequent surgery or intervention) was achieved in 200 (82.6%) of the patients in the disc replacement group and in 161 (72.9%) of those in the fusion group (p = 0.01). Complications occurred in 75 (31.0%) of the patients in the disc replacement group and in 61 (27.6%) of those with an anterior discectomy and fusion. These were mainly unrelated to the surgical procedure, implant or cervical spinal disease but related to general medical conditions. Only four of the disc replacement group and seven of the fusion group had adverse events related to the implant or the surgical procedure. Secondary procedures at the operated level were performed in six of the disc replacement group (1 revision, 3 removals and 2 re-operations) and in eight of the anterior discectomy and fusion group (3 removals, 1 re-operation and 4 supplemental fixations). This difference was not statistically significant. A total of 117 patients (37 in the disc replacement group, and 80 in the discectomy and fusion group) declined to participate in the study before receiving the assigned treatment. The randomisation was performed before surgery allowing the patient to refuse the proposed treatment if not satisfied with the group they were allocated to. This caused the withdrawal of 32 patients in the fusion group, but none in the cervical disc replacement group.

The precursor of the Prestige implant was a metal-on-metal ball and socket articulation called the Cummins/Bristol cervical disc. A second-generation device, the Prestige I, was developed in 1998 and included a mechanism for anteroposterior translation coupled with sagittal flexion-extension and rotation. The Prestige I implant is a coupled, semi-constrained, metal-on-metal device. It consists of a metal ellipsoid which articulates with a recessed surface on the superior component. The implant has undergone several changes. A later version, the Prestige II disc, was designed in 1999 and has a more anatomical design at the endplates. A further version, with smaller anterior flanges the PRESTIGE ST, was introduced in 2002. Currently, the Prestige LP (low profile) is the variant implanted in Europe (Fig. 2).

The original Cummins/Bristol device was developed for patients whose disc degeneration was adjacent to a previous fusion, and for patients with the Klippel-Feil Syndrome. In one study 22 devices were implanted in 20 patients. After five years, 16 of the 18 (88.9%) available showed significant clinical improvement and preservation of movement at the mobile segment. The reported complications included screw loosening or breakage, subluxation of the implant, dysphagia, transient hemiparesis (caused by the drill) and loosening of the implant requiring revision.

In a case-control study comparing the use of the Cummins/Bristol cervical disc replacement device with spinal fusion, there was no apparent progression of degeneration of the adjacent segment, and no significant difference between the two groups. A multicentre study of 541 patients with a radiculopathy from single-level degenerative disc disease compared the use of the PRESTIGE ST cervical disc replacement in 276 patients with anterior discectomy and fusion in 263 patients. After two years, data from 421 patients were available (223 of the 276 in the disc replacement group and 198 of the 265 in the discectomy and fusion group). The former group had better clinical results and better neurological function whilst maintaining movement at the affected level. There were fewer revision procedures in the disc replacement group (n = 5) than in the discectomy and fusion group (n = 23) and less revision surgery for adjacent disc disease in the disc replacement group (3 of 276) than in the discectomy and fusion group (9 of 265).

The ProDisc-C (Fig. 3) consists of two end-plates of a cobalt-chromium-molybdenum alloy and an articular surface of metal-on-polymer bonded to the bottom plate. The end-plates are plasma-sprayed with titanium to allow bone ingrowth. A central metallic keel projects from each end-plate into the vertebral body and helps to maintain the primary stability of the implant. Early results from a single-centre case series showed a significant improvement in pain and outcome score. A recent study comparing the results of the Prodisc-C with those of anterior discectomy and fusion showed no complications related to the use of the implant, no adjacent disc degeneration and good clinical results at three years in both groups. There was no difference in the results when it was used at one or more levels. Recently, a two-year prospective, randomised, controlled multicentre study compared the use of the ProDisc-C cervical disc replacement with anterior discectomy and fusion with allograft for single-level symptomatic disease. There was a statistically significant difference in the number of revision procedures in the two groups, 8.5% (9 of 106) of the anterior discectomy and fusion group and 1.9% (2 of 103) of the disc replacement group. The ProDisc-C was successful in 73.5% (76 of 103) and anterior discectomy and fusion and plating in 60.5% (64 of 106) at follow-up at 24 months.
intubation injury. 6

Table I. Incorrect indicators for cervical disc replacement

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthritis of facet joints</td>
<td>2.91%</td>
</tr>
<tr>
<td>Pre-operative instability</td>
<td>2.91%</td>
</tr>
<tr>
<td>Systemic diseases (osteonerosis and inflammatory diseases)</td>
<td>2.91%</td>
</tr>
<tr>
<td>Previous posterior surgery</td>
<td>2.91%</td>
</tr>
<tr>
<td>Advanced age</td>
<td>2.91%</td>
</tr>
<tr>
<td>Ossification of the posterior longitudinal ligament</td>
<td>2.91%</td>
</tr>
<tr>
<td>Myelopathy</td>
<td>2.91%</td>
</tr>
</tbody>
</table>

Table II. Complications related to cervical spinal arthroplasty

| Related to the surgical approach (same as anterior discectomy and fusion) | Infections, lesions to the deep structures of the neck, neurological lesions, vascular lesions, dysphagia |
| Related to the surgical technique | Wrong positioning of the implant |
|                                   | Wrong size of device |
|                                   | Post-operative kyphosis |
|                                   | Migration |
|                                   | Persisting neurological deficit |
|                                   | Subsidence |
| Related to the implant            | Mobilisation |
|                                   | Failure of the implant |
|                                   | Debris |
|                                   | Periprosthetic ossifications |

Complications

Most complications arise from errors in the selection of patients (Table I). 21 Earlier studies of disc replacement surgery in small series reported no complications, 22,23 but these findings have not been confirmed by subsequent study on larger populations. 24,25 In the European study, some of the most frequently reported complications were related to the use of the anterior approach. 6 In this study, 103 patients were operated using a single-level implant and 43 patients two-level implants. In the single level group, 0.97% (1 of 103) patients were re-operated to evacuate a prevertebral haematoma; moreover, 2.91% (3 of 103) patients required a adjunctive surgery, namely one posterior decompression one posterior foraminotomy for persistent neural compression, and one underwent re-operation for wrong level surgery. In the two-level group, 2.33% (1 of 43) patients had a dural tear during decompression, 2.33% (1 of 43) patients had further surgery for epidural haematoma and 2.33% (1 of 43) for evacuation of a prevertebral haematoma. One patient of 43 (2.33%) required pharyngeal/oesophageal wound repair due to intubation injury. 6

Other complications are specifically related to the device (Table II). Prevertebral ossification with ankylosis has been widely reported. In a European multicentre study of the Bryan cervical disc replacement 16 patients (17.8%) experienced this complication. 26 Pre-existing spondylosis and segmental ankylosis are recognised risk factors, together with male gender and increased age. 26 Administration of non-steroidal anti-inflammatory drugs for two to three weeks after the operation decreases the tendency to spontaneous ankylosis. 27 In the lumbar spine, the incidence of spontaneous ankylosis after total disc replacement can be up to 60% at 17 years, but no long-term results for cervical disc replacement are available to date. 28

Neurological deficit after cervical disc replacement is rare, and is usually the result of inadequate root decompression at the neural foramen. 6 In one study this was present in seven of 11 failures (63.6%) all with the Bryan implant. 1 Other authors have reported neurological symptoms after cervical disc replacement which include radicular pain, limb weakness and decreased sensation. In both instances, imaging failed to show the cause of these symptoms. In another patient with implants at two levels, a worsening myelopathy was noted. This was attributed to inadequate decompression of a superior osteophyte and focal kyphosis. The patient was treated with steroids. 29

Patients in whom the cervical spine has lost its physiological lordosis or is kyphotic pre-operatively are at increased risk of post-operative kyphosis. 30 This is almost certainly due to inadequate preparation of the end-plate, which influences the angle of insertion of the device. 29 In a recent study of 47 patients with a Bryan cervical disc replacement only ten of 28 patients (35.7%) with a pre-operative segmental lordosis remained lordotic at late follow-up. Of the eight patients with a pre-operative segmental kyphosis, five remained kyphotic pre-operatively whereas 36 of 40 patients (90%) with cervical lordosis pre-operatively remained lordotic. Of three patients with cervical kyphosis pre-operatively, one was corrected, one had straight alignment and the third remained kyphotic. 31

Subsidence can occur in patients who are osteoporotic. It is related to the footprint of the device and the way in which the end-plate has been prepared. 32 The footprint of the implant should be as large as possible to maintain the axial load. Subsidence of the cervical disc replacement has not, to our knowledge, been reported to date.

Several authors have reported failure of the device, loss of segmental mobility, and loosening of the implant. 6,29 Goffin et al reported anterior migration of the device in three of 146 patients, loss of segmental mobility in 11 of 90 with a single-level implant, and in seven of 49 with a two-level implant after one year. In a recent prospective trial comparing the Bryan cervical disc replacement with anterior discectomy and fusion with allograft and plate, 13 of 191 patients (7%) with cervical disc replacement available at two years had lost ROM at the affected segment and had ≤ 2° of movement on lateral flexion/extension radiographs. 33

Patients undergoing any joint replacement produce debris which can initiate an inflammatory reaction. 34 This in turn can lead to pain, osteolysis and loosening of the implant. 35 The effect of osteolysis on cervical disc replacement is currently unknown. 36
As with lumbar disc replacement, the use of a keeled device increases the risk of producing a fracture which splits the vertebra. A small vertebral body, osteoporosis or metabolic bone disease and a poor surgical technique are thought to be risk factors.

Other possible complications such as slight anterior migration, abnormal loading and wear of the polyethylene and the development of degenerative spondylolisthesis, may require revision surgery. This is a major issue in joint replacement surgery and in lumbar disc replacement, but is even more daunting in the cervical spine. The cervical disc replacement is designed for the young healthy patient with disc degeneration who may require several revisions during their lifetime. Various revision strategies have been reported, all of which require the conversion of the replaced segment to a fusion. Patients who develop radiculopathy may benefit from a posterior foraminotomy alone. To date, only a few revision procedures which remove the implant have been performed. Because cervical implants undergo osseointegration, at revision the surgeon has to address the inevitable loss of bone stock, which may prejudice the outcome of the procedure.

Discussion

The rationale behind the use of disc replacement rather than anterior cervical discectomy and fusion is dependent on the maintenance of segmental movement and on the prevention of degeneration in movement segments adjacent to a previous fusion.

Segmental stability and movement. The artificial disc should resemble the native disc in its ability to allow movement and to maintain stability of the motion segment.

The anterior elements of the cervical spine mainly contribute to stability in extension, while the posterior ligaments exert their function in flexion. If the soft tissues of the cervical spine are sectioned from front to back (as in a discectomy), the spine becomes unstable after sectioning of the anterior longitudinal ligament, annulus and the posterior longitudinal ligament. Studies in which the posterior longitudinal ligament annulus complex has been disrupted have also caused segmental instability, suggesting that the integrity of the posterior longitudinal ligament is the major determinant of segmental stability.

The symptoms which accompany cervical disc degeneration are probably caused by posterior osteophytes, and not by direct herniation of the nucleus pulposus. These calcified ‘hard discs’ often adhere to the posterior longitudinal ligament, which may be sectioned when both disc and posterior osteophytes are removed to decompress the neural structures. If this happens, fusion should be undertaken rather than a disc replacement to prevent post-operative instability.

The global range of movement in the cervical spine varies widely with ranges between 130° and 145° of flexion and extension, 90° of lateral flexion and 160° and 180° of axial rotation on both sides. Sagittal flexion/extension mainly occurs at the C0-2 segment, while the other segments are only responsive for a few degrees of movement each (Table II). The segmental and the global ROM of the cervical spine vary according to age and disc degeneration, with a greater ROM in adolescents than in adults. There is also a gradual but significant loss of movement in all planes in healthy asymptomatic individuals aged between 35 and 39 years compared with those aged between 50 and 54 years. The ROM is also inversely affected by body habitus, increase in body weight and decrease in the level of sporting activities. The healthy cervical spine moves more than that affected by degenerative disc disease or radicular compression. Consequently, immobilisation of a single segment seems to have little effect on the global ROM of the cervical spine, especially in patients with a spine which is stiff preoperatively. Further studies are required to understand cervical spine kinematics and reproduce the physiological range of motion with a cervical spine arthroplasty.

Adjacent segment degeneration. Disc degeneration which occurs at a level adjacent to a previous fusion may be the result of overload of the adjacent disc. This, however, is a matter of controversy. Some authors have reported no change in the extent of adjacent segment movement two years after a fusion. Experimental studies on cadaver cervical spines have shown that single-level fusion results in a uniform increase of movement in all the remaining mobile units. By contrast, fusion also seems to lead to a significant increase in intradiscal pressure of the adjacent discs during the physiological ROM, leading to early disc degeneration. In this context several studies have addressed the natural history of the adjacent intervertebral disc.

In a study on anterior cervical discectomy and fusion using Cloward’s technique, degenerative disease of the adjacent level was found in 32 of 100 patients (32.0%) after ten years. Contrary to the observations of Goffin et al, all these patients were asymptomatic.

In another study of anterior cervical discectomy and fusion for degenerative disc disease, symptomatic adjacent disc degeneration occurred in 58 of 409 (14.2%) patients. Of these, only 29 (7.1%) required further surgery. Adjacent level degeneration was thought to be the physiological progression of intervertebral disc degeneration, and unrelated to the fusion. These findings have been confirmed by one long-term follow-up study, in which further surgery for adjacent segment degeneration was necessary in eight of 50 patients (16.0%). In a study with a follow-up for between three and 18 years it was shown that the occurrence of adjacent level degeneration was influenced only by the age of the patient. The occurrence of degeneration adjacent to a previous fusion appears to be dependent on two factors, namely, the level of the affected disc, given that discs distal to the fused vertebrae are more mobile and more prone to overload, and the hydration of the adjacent disc at the time of fusion, as shown on T2-weighted MRI. In discs which are already dehydrated, the risk of develop-
ing intervertebral disc disease is increased. This observation is consistent with the natural history of intervertebral disc degeneration in the cervical spine, which begins after the second decade of life and evolves slowly, often in an asymptomatic fashion.64 These findings have been confirmed by a recent study66 on the Bryan cervical disc replacement in 78 patients with follow-up for four to six years.

It is likely that a major risk factor for adjacent segment disease is post-operative segmental malalignment after fusion, given that adjacent degeneration is most commonly seen in patients with kyphosis and sigmoid curves, rather than in those with post-operative lordosis.67 Similarly, patients with Klippel-Feil syndrome may have intervertebral disc degeneration adjacent to the ‘block vertebra’ but surgery is rarely required, unless an axial deformity is present.68 To date, there have been only a few studies which have examined the ability of cervical disc replacement to prevent adjacent segment degeneration.11,16,20,69 Despite encouraging preliminary results, longer term studies are needed to validate its use and document long-term problems.

Cervical fusion is one of the more successful operations in orthopaedics, with success rates of up to 95% in patients affected by single-level degenerative disc disease.1,58 Despite the different techniques used and number of levels fused anterior discectomy and fusion remains a safe and reliably successful procedure.70 In conventional cervical spinal surgery for disc degeneration, the segment is fused not just to fill the gap left by the decompression, but also to stabilise the segment.34,45 The impact of fusion on overall cervical spinal movement is minimal65 but it serves to prevent further myeloradiculary disease by allowing the spinal cord to recover from local damage manifest as myelopathy with or without myelomalacia.21

The long-term outcome of fusion has been misrepresented, since disc degeneration in the adjacent cervical segments has limited clinical impact, and adjacent disc degeneration may be the result of a pre-existing degenerative process.2 The indication for cervical disc replacement should be limited to the prolapsed cervical disc in a young patient in whom the disc height is preserved, while bearing in mind that revision is likely to be more complex than for other joints. The long-term results of cervical disc replacement suggest that up to 60% of implants are ankylosed at 17 years.78

There is a lack of long-term evidence of the efficacy of cervical disc replacement. Only prospective, randomised trials with long-term follow-up, as are required for total joint replacement surgery, will establish any advantage of cervical disc replacement over anterior cervical discectomy and fusion. At present, only a few prospective, randomised studies on large groups of patients have been carried out and follow-up has been limited to two years.

On the basis of the available reports, and despite the possible complications from replacement surgery of the cervical disc, disc replacement seems to be successful in the management of single-level cervical spinal radiculopathy, but not myelopathy, from disc herniation or osteophytes. At operation, the surgeon should consider fusion of the motion segment if the posterior longitudinal ligament is divided when removing the posterior osteophyte, given the risk of iatrogenic segmental instability if cervical disc replacement is performed.

References


