

REVIEW ARTICLE

Complications of Bryan cervical disc replacement

Jun-ming Cao MD, Ying-ze Zhang MD, Yong Shen MD, Wen-yuan Ding MD

Department of Spine Surgery, The Third Hospital of Hebei Medical University, Shijiazhuang, China

The primary goals of cervical disc replacement are to avoid fusion in the affected segment, maintain the mobility and function of the involved cervical segments, allow patients to quickly return to routine activities and reduce or eliminate adjacent-segment disease. A large number of patients have already undergone, and more and more patients will in the future undergo, cervical disc replacement. The cervical device which best preserves movement, and has therefore been the device of choice, has been the Bryan cervical disc. Although a safe surgical technique has been demonstrated and favorable results of using the Bryan disc reported, some complications have also accompanied this arthroplasty. Complications of Bryan cervical disc replacement include those related to the operative approach and decompression process, loosening and failure of the device, postoperative kyphosis, heterotopic ossification, and loss of movement due to spontaneous fusion. In order to avoid these complications, strict patient selection criteria and a meticulous knowledge of anatomy are necessary.

Key words: Arthroplasty; Cervical vertebrae; Postoperative complications; Prostheses and implants

Cervical disc replacement is used to treat degenerative cervical disc disease in an attempt to preserve cervical movement of the affected segment and to prevent overload of the adjacent disc and subsequent degeneration^{1–6}. According to the current criteria for cervical disc replacement, it has been estimated that the procedure would be performed in 43% of patients who require surgery for degenerative conditions of the cervical spine⁷.

The cervical device which best preserves movement, and has therefore been the device of choice, has been the Bryan cervical disc. The Bryan cervical disc also has the longest reported clinical and radiological follow-up. The first clinical studies began in January 2000 in Europe (Belgium, Italy, Germany, Sweden, UK and France)⁸ and the first prospective, multicenter clinical trial of Bryan cervical disc replacement for single-level degenerative disease was published in 2002⁴. However, in Goffin's study only 30 of the 97 recruited patients were available for follow-up after one year and of these, full clinical and radiological data was available for only 24⁴. Some movement was preserved after one year in 21 of the patients (87.5%). In a further paper with longer follow-up and using implants at two levels, similar results were obtained⁹. 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.

Bryan cervical disc replacement was initially performed in patients with radiculopathy^{4,9}. More recently, it has been performed in patients with myelopathy¹⁰; reported results have been better in patients with radiculopathy than in those with myelopathy. Recently, a number of papers have reported procedures using the Bryan disc in patients with radiculopathy or myelopathy^{3,5,6,9,11–18}. The implant has preserved the segmental range of movement, the clinical results have been similar to those achieved with fusion, and the surgical technique has been demonstrated to be safe¹³. Although Bryan cervical disc arthroplasty has been shown to yield favorable clinical results following one- and two-level disc replacement, various complications do occur. Complications of Bryan cervical disc replacement include those related to the operative approach and decompression process, loosening and migration of the device, subsidence of the implant, postoperative kyphosis, heterotopic ossification, and loss of movement due to spontaneous fusion.

Complications related to the operative approach

Because the approach for Bryan cervical disc replacement is identical to that of anterior cervical discectomy (ACD) and cervical arthroplasty with any type of cervical prosthesis, the complications related to operative approach are similar. Various complications related to the

Address for correspondence Yong Shen, MD, Department of Spine Surgery, The Third Hospital of Hebei Medical University, 139 Ziqiang Road, Shijiazhuang, China 050051 Tel: 0086-311-88602016; Fax: 0086-311-88603632; Email: cjmspine@yahoo.com.cn

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anterior cervical operative approach have previously been reported. The list of reported postoperative complications includes dysphagia, wound hematoma, recurrent laryngeal nerve (RLN) palsy, Horner's syndrome, pharyngeal or esophageal laceration, thoracic duct injury, angioedema, respiratory insufficiency, vertebral artery (VA) laceration, carotid artery or jugular vein injury, aneurysm formation, epidural hematoma, superficial or deep wound infection, dural laceration, and cerebral spinal fluid (CSF) leakage^{19–44}.

Postoperative dysphagia is the most common postoperative complaint reported. Its reported incidence has ranged widely between 2% and 67% among various clinical series^{24,39,45–56}. The development of postoperative wound hematoma is the second most common, and potentially catastrophic, complication. Its incidence among previously reported series varies between 1% and 11%^{19,55,57–65}. RLN palsy also represents one of the most commonly reported ACD-related complications^{19,22–30}. The use of careful, periodically released, handheld retraction may result in a low rate of RLN palsy⁵⁵. Spontaneous recuperation of the palsy occurs in the majority of these patients according to our clinical experience. VA injury during an ACD has been reported to be as high as 0.3%^{22,31,32,41–43}. Development of postoperative Horner's syndrome occurred in 0.1%, 0.2%, and 1.1% of patients in Fountas', Tew's, and Bertalanffy's studies, respectively,^{19,23,55}. It has been postulated that Horner's syndrome can be avoided if subperiosteal dissection of the longus colli muscle is performed⁶⁶.

Accurate early identification and prompt appropriate management of these potential complications are imperative for accomplishing a good outcome in these patients, and appropriate management of any procedure-related complications requires meticulous knowledge of anatomy.

Complications related to the decompression process

Complications related to the decompression process include spinal cord or nerve root injury and inadequate decompression. Neurological deficit after cervical disc replacement is rare, and is usually the result of inadequate root decompression at the neural foramen^{9,67}. In the case of the procedure of Bryan cervical disc replacement, the most important reason for these complications is the limited scope for decompression imposed by the need to preserve the endplates completely. One patient in Shim's study had persistent arm pain due to incomplete decompression which necessitated revision⁶⁷. The

revision consisted of removal of the implant, further decompression of the neural foramen and reimplantation of the device. The patient recovered without sequelae. Anderson and Rouleau reported that complications related to the decompression process were present in seven of 11 failures (63.6%) with the Bryan implant². Other authors have reported neurological symptoms after cervical disc replacements which include radicular pain, limb weakness and decreased sensation. In another patient with implants at two levels, a worsening myelopathy was noted and revision surgery was required for decompression of residual foraminal stenosis⁹. Decompression is the primary purpose of treatment of cervical disease. The Bryan prosthesis is designed to retain cervical movement of the affected segment, and requires complete preservation of the end plate. Because inadequate root decompression at the neural foramen often develops in Bryan cervical disc replacement, adequate neural foramen decompression in this procedure is crucial.

Prosthesis loosening and migration

The Bryan disc system was engineered to provide immediate lateral and anteroposterior stability through capture of the convex shells within the concavities milled in the vertebral endplates. Several authors have reported failure of the device due to loosening and migration of the implant^{9,10,15}. Goffin *et al.* reported migration of the device in three of 146 patients, and confirmed that a deficiency in the endplate milling process was the reason for migration⁹. However, migration greater than 3.5 mm has not been observed in any patients; this threshold is based on the definition of segmental integrity^{68,69}. In a case where posterior migration of the shell occurred, Pickett *et al.* suggested that extensive posterior decompression may have undercut the vertebral body to the extent that endplate milling did not reestablish a posterior rim that was adequate to hold the shell in place¹⁵. Although the anterior stop of the disc is designed to prevent its posterior migration, it may not be reliable in all cases. Patients undergoing any joint replacement produce debris which can initiate an inflammatory reaction⁷⁰. This in turn can lead to pain, osteolysis and loosening of the implant^{71,72}. A small vertebral body and poor surgical technique are thought to be risk factors.

It is inevitable that prosthesis loosening will occur in patients with osteoporosis or metabolic bone disease. Therefore we should remember that osteoporosis and metabolic bone diseases are contraindications to the use of cervical arthroplasty.

Subsidence of the implant

Subsidence is defined as sagging of the device into the milled vertebral endplates. Subsidence of the implant can result in loss of movement of the affected segment and overload of the adjacent disc, thereby leading to surgical failure. With the wide application of cervical artificial disc replacement, subsidence demands more and more attention from orthopedic surgeons. Subsidence can occur in osteoporotic patients. It is related to the footprint of the device and the way in which the end-plate has been prepared⁷³. An *in vitro* biomechanical study showed that the implant interface plays an important role in the magnitude of subsidence of a device and that there is a significant loss of endplate integrity when 1 mm (44% loss) or 2 mm (52% loss) of endplate has been removed⁷⁴. Fortunately, subsidence of cervical disc replacement has not, to our knowledge, been reported to date. This may be related to the low axial stress in the neck.

According to our experience, strategies to prevent these complications are as follows. The footprint of the implant should be as large as possible to maintain the axial load. Sufficient end-plate processing is necessary. The end-plate cartilage should be completely scraped off, but the osseous endplates should not be resected too much or overmilled. It is important to keep in mind that osteoporosis is a contraindication to arthroplasty.

Other possible complications, such as abnormal loading and wear of the polyethylene and the development of degenerative spondylolisthesis, may require revision surgery⁶. This is a major issue in joint replacement surgery and in lumbar disc replacement, but is even more daunting in the cervical spine. Cervical disc replacement is designed for the healthy young patient with disc degeneration who may require several revisions during their lifetime. Various revision strategies have been reported, all of which require conversion of the replaced segment to a fusion. To date, only a few revision procedures in which the implant is removed have been performed. Because cervical implants undergo osseointegration⁷⁵, at revision the surgeon has to address the inevitable loss of bone stock, which may prejudice the outcome of the procedure. Patients who develop radiculopathy may benefit from a posterior foraminotomy alone⁷⁶.

Postoperative kyphosis

Numerous studies reporting adverse outcomes of cervical arthroplasty have stated that postoperative kyphosis frequently develops^{1,12,73,77–80}. There are two aspects to such kyphosis: segmental malalignment of the functional

spinal unit (kyphosis of the FSU) and prosthetic shell angle of the Bryan prosthesis (kyphosis of the shell).

Segmental kyphosis is significantly more common after anterior cervical discectomy without arthrodesis⁸¹, and the frequency of occurrence is similar after Bryan cervical disc arthroplasty. Sears *et al.* observed a small loss in median FSU lordosis after insertion of the Bryan disc⁸². Pickett *et al.* reported that 100% of their 14 patients implanted with the Bryan disc developed segmental kyphosis persisting beyond 6 months follow-up, although the range of movement (ROM) at the replaced levels was preserved¹².

The shell angle, which represents the angle of the disc space, can become kyphotic after surgery, resulting in segmental kyphosis, even when the Cobb angle from C_{2–7}, which measures spinal alignment in the sagittal plane, is preserved⁸³. Pickett *et al.* found a significant relationship between the FSU and shell endplate angles¹². They reported a mean change in the shell endplate angle of -3.8° and found that the FSU angle became significantly more kyphotic, with a mean change of -6° .

In the relatively short-term study, no statistically significant adverse clinical outcome is caused by postoperative kyphosis^{12,84}. However Shim *et al.* predicted that segmental kyphosis would have more of a negative influence on the cervical spine than segmental lordosis⁶⁷, as it is well known that long-standing cervical kyphosis can produce myelopathy with resultant permanent damage to the spinal cord^{85–88}. Van Ooij *et al.* reported facet joint arthrosis as a late complication of lumbar disc arthroplasty⁸⁹. There is also an increase in the overall range of cervical spinal movement due to an increase in movement of the adjacent discs. Troyanovich *et al.* believed the adjacent level and other segments would provide compensation for the kyphotic segment, and that in so doing they would bear more stress while preserving overall sagittal alignment, which would accelerate the degenerative process⁹⁰. Reports have also indicated that the risk of development of axial symptoms after anterior cervical discectomy with or without fusion is significantly related to cervical kyphosis^{12,91,92}. Harrison *et al.* also found a relationship between cervical kyphotic and axial neck pain in patients who had not undergone surgery⁹³.

Some recent studies have reported and analyzed the factors contributing to postoperative FSU kyphosis, such as overmilling at the dorsal endplate, the angle of Bryan disc insertion, and the surgical procedure of removing the entire posterior longitudinal ligament^{1,12,73,78–81}. Patients in whom the cervical spine has lost its physiological lordosis or is kyphotic preoperatively are at increased risk of postoperative kyphosis^{94,95}. Sears *et al.* found that the variables which they believe may contribute to postoperative

sagittal alignment, such as postoperative change in disc space height, angle of prosthesis insertion, and the amount of bone removed from the anterior aspect of the cephalad vertebra, varied significantly between different surgeons and correlated with changes in FSU alignment^{82,91}. Thus, Pickett *et al.* suggested that careful patient selection and attention to the angle of insertion should reduce the risk of postoperative kyphotic deformity and its attendant problems¹⁵.

We have also studied the radiographs of our cases which did not develop kyphosis, and have found that overmilling of the endplate and asymmetric milling were the two main contributing factors of endplate kyphosis⁸⁴. So, in a prospective study, we modified our techniques to avoid kyphosis, including avoiding overmilling of the end-plate and asymmetric milling by changing the insertion angle in our patients. When we inserted the Bryan prosthesis parallel to the angle of the native disc space, the neutral shell angle and the neutral FSU angle changes in the investigational group were significantly more lordotic than they were in the control group⁸⁴. Thus, cervical alignment can be improved if the Bryan prosthesis is inserted along a line parallel to the superior endplate of the caudal vertebral body at the implanted level rather than inserted, as described in the manufacturer's insertion guide, along a line perpendicular to the line connecting the posterior inferior corner of the caudal vertebral body and the posterior superior corner of the cephalad vertebral body.

Heterotopic ossification and spontaneous fusion

There are several reports on heterotopic ossification (HO) around the Bryan disc with some impact on the clinical results^{8,15,96–101}. Pickett *et al.* reported that two cases (2.7%) developed fusion due to posterior bridging osteophytes which were demonstrated by radiography at an average of 1 year follow-up¹⁵. In a European multicenter study of Bryan cervical disc replacement, 16 patients (17.8%) experienced prevertebral ossification with ankylosis after 1 year follow-up¹⁷. The patients in Parkinson and Sekhon's study developed HO 17 months after Bryan cervical spinal disc arthroplasty¹⁰⁰. Bryan's study showed some evidence of paravertebral ossification in about 30% of patients⁸. Sola *et al.* reported that 16 of 21 (76.2%) affected segments had developed HO three years after Bryan cervical spinal disc replacement. In the lumbar spine, the incidence of spontaneous ankylosis after total disc replacement can be as much as 60% at 17 years¹⁰², but no long-term results for cervical disc replacement are yet available. Mehren *et al.* recently published a classification system for lumbar total disc replacement which classifies

heterotopic ossification into five grades¹⁰¹. Only 33.8% of the patients showed no signs of heterotopic ossification in their two center prospective clinical study.

HO can develop into spontaneous fusion, which is the primary factor causing loss of segmental mobility. Preservation of mobility after arthroplasty is only guaranteed if spontaneous fusion can be prevented. Several authors have reported loss of segmental mobility^{9,15,103}. Four percent of cases had loss of segmental mobility in Pickett's study¹⁵. Goffin *et al.* reported 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 year⁹. In a recent prospective trial comparing 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 $\leq 2^\circ$ of movement on lateral flexion/extension radiographs¹⁰³. Leung *et al.* have pointed out that occurrence of HO is strongly associated with subsequent loss of movement of the implanted cervical artificial disc⁹⁹.

Although the precise reasons for HO are unknown, pre-existing spondylosis and segmental ankylosis, together with male gender and increased age, have been recognized to be risk factors⁹⁹. This is similar to the risk factors in total hip replacement and spinal cord injuries^{104,105}. Occurrence of HO may also be related to smaller sizes of prosthesis; alternatively, these patients may have been predisposed to fusion, as there was preoperative evidence of calcification of the posterior longitudinal ligament¹⁵. One theory about HO implicates residual bone dust left behind at the operative site¹⁰⁶. This may be relevant in the Bryan disc procedure, where there is fairly extensive drilling of the endplates (parallel), followed by circular milling. To compensate for this problem, copious irrigation of the operative site with normal saline during milling and again before closure is recommended^{99,107}. Leung *et al.* have also suggested that injuries to, and inflammatory responses of, the longus colli due to excessive retraction during surgery may be one of the factors which can lead to the development of HO⁹⁹. Additionally, administration of non-steroidal anti-inflammatory drugs postoperatively can profoundly reduce the incidence of paravertebral ossification^{8,101}.

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