Clinical Policy Bulletin: Intervertebral Disc Prostheses

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Policy

I. Aetna considers FDA-approved prosthetic intervertebral discs (e.g., MOBI-C, Secure-C Artificial Cervical Disc, ProDisc-C Total Disc Replacement, Bryan Cervical Disc) medically necessary for the treatment of skeletally mature persons with symptomatic (e.g., radicular neck and/or arm pain and/or functional/neurological deficit) cervical degenerative disc disease or hemiated disc at one level from C3 to C confirmed by radiographic studies (e.g., CT, MRI, x-rays), and who have failed at least 6 weeks of conservative management.

II. Aetna considers lumbar prosthetic intervertebral discs (e.g., the Charite Artificial Disc, and the ProDisc-L Total Disc Replacement) experimental and investigational for lumbosacral degenerative disc disease and for all other indications.

III. Aetna considers prosthetic intervertebral discs experimental and investigational for persons who have degenerative disk disease at more than one level.

IV. Aetna considers lumbar partial disc prosthetics (e.g., Nubac, DASCOR Disc Arthroplasty System) experimental and investigational because of insufficient evidence of their effectiveness.

V. Aetna considers concurrent or planned sequential artificial cervical disc replacement with cervical spinal fusion (experimental and investigational for the management of neck pain spinal disorders, and all other indications.

See also CPB 0016 - Back Pain - Invasive Procedures, and CPB 0743 - Spinal Surgery: Laminectomy and Fusion.

Background

Since the 1970s, investigators have been working on developing an artificial prosthetic intervertebral disc (IVD) that can be used to replace degenerated intervertebral discs (Diwan, et al., 1997). Most of the published clinical evidence for artificial prosthetic intervertebral discs has been of those that replace the entire disc.

The major potential advantage of a prosthetic intervertebral disc over current therapies for degenerated disks (such as spinal fusion or disectomy) is that the prosthetic intervertebral disk is intended to restore or preserve the natural biomechanics of the intervertebral segment and to reduce further degeneration of adjacent levels.
van Ooij et al (2003) reported a series of 27 patients who presented with unsatisfactory results or complications after Charite disc replacement. Most patients were operated on at the L4 - L5 and/or the L5 - S1 vertebral levels. The patients were evaluated with plain radiography, some with flexion-extension x-rays, and most of them with computed tomography scans. The group consisted of 15 women and 12 men. Their mean age was 40 years (range, 30 - 67 years) at the time of operation. The patients presented to the investigators a mean of 53 months (range 11 - 127 months) following disc replacement surgery. In two patients, an early removal of a prosthesis was required and in two patients a late removal. In 11 patients, a second spinal reconstructive salvage procedure was performed. Mean follow-up for 26 patients with mid- and long-term evaluation was 91 months (range 15 - 157 months). Early complications were the following: In one patient, an anterior luxation of the prosthesis after 1 week necessitated removal and cage insertion, which failed to unite. In another patient with prosthesis at L4 - L5 and L5 - S1, the prosthesis at L5 - S1 dislocated anteriorly after 3 months and was removed after 12 months. Abdominal wall hematoma occurred in four cases. Retrograde ejaculation with loss of libido was seen in one case and erection weakness in another case. A temporary benefit was experienced by 12 patients, while 14 patients reported no benefit at all. Main causes of persistent complaints were degeneration at another level in 14, subsidence of the prosthesis in 16, and facet joint arthrosis in 11. A combination of pathologies was often present. Slow anterior migration was present in two cases, with compression on the iliac vessels in one case. Polytene wear was obvious in one patient 12 years after operation. In eight cases, posterior fusion with pedicle screws was required. In two cases, the prosthesis was removed and the segment was circumferentially fused. These procedures resulted in suboptimal long-term results. In this relatively small group of patients operated on with a Charite disc prosthesis, most problems arose from degeneration of other lumbar discs, facet joint arthrosis at the same or other levels, and subsidence of the prosthesis.

Caspi et al (2003) reported results of lumbar disk prosthesis (Charite) after a follow-up period of 48 months. These investigators found that 80% of patients reported satisfactory to very good results. Poor results were reported by four patients, one of whom underwent postero-lateral fusion and another is waiting for the same operation. There were two dislocations of the prosthesis followed by immediate revision surgery. The authors concluded that contraindications for surgery appear to be the principal cause of failure rather than the prosthesis itself.

In a multi-center, prospective, randomized investigational device exemption study of the Charite intervertebral disc, Geisler et al (2004) compared the Charite artificial disc with lumbar fusion using the BAK cages in patients with lumbar degenerative disc disease (n = 304). The authors found that the neurological status was equivalent between the two groups at 6, 12, and 24 months, post-operatively. They concluded that the Charite intervertebral disc is safe and effective for the treatment of single-level degenerative disc disease, resulting in no higher incidence of neurological complications compared with BAK-assisted fusion, and leading to equivalent or better outcomes (as indicated by visual analog scale and Oswestry Disability Index scores) compared with fusion with those obtained in the control group and those reported in the lumbar fusion literature. The authors concluded that the findings of this study is promising, but that longer follow-up is needed to determine the durability of the Charite artificial disc and its long-term safety and effectiveness.

The United States Food and Drug Administration (FDA) has approved the Charite Artificial Disc for spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. The indications for the Charite define DDD as discogenic back pain with degeneration of the disc that is confirmed by patient history and radiographic studies. According to the FDA-approved labeling, these DDD patients should have no more than 3 mm of spondylolisthesis at the involved level. The FDA approved labeling states that patients receiving the Charite Artificial Disc should have failed at least six months of conservative treatment prior to implantation of the Charite Artificial Disc.

The Charite Artificial Disc was approved by the FDA based on a clinical trial comparing the device to anterior lumbar interbody fusion (ALIF) with BAK cages filled with iliac crest autograft in subjects with symptomatic single level degenerative disc disease from L4 to S1 who had failed at least 6 months of conservative management. The purpose of the study was to demonstrate the non-inferiority of the Charite Artificial Disc to an interbody fusion.
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A total of 304 patients were enrolled in the study using a 2:1 (Charite to BAK) randomization scheme. On hundred eighty four subjects receiving the Charite Artificial Disc and 81 subjects receiving interbody fusion (control completed 24 months follow up. Safety of the Charite Artificial Disc was assessed by monitoring the intraoperative and postoperative complications, including infection, thrombosis, disc migration, and disc subsidence, as well as reoperation and other adverse events. Efficacy of the Charite Artificial Disc was assessed primarily by a success criteria comprised of: level of disability (Oswestry Low Back Disability Index (ODI)), neurological assessment (functional status) and information from adverse event data. To be considered an overall success, a subject must have had: 1) an improvement of at least 25% in the ODI score at 24 months compared to baseline; 2) no device failures requiring revision, reoperation, or removal; 3) absence of major complications, defined as major blood vessel injury, neurological damage, or nerve root injury; and 4) maintenance or improvement in neurological status at 24 months, with no new permanent neurological deficits compared to baseline. Based on these criteria, the overall success rate was 64% for subjects receiving the Charite Artificial Disc and 57% for control subjects receiving interbody fusion. The FDA requested that the data be analyzed and reported using an improvement in the Oswest Disability Index of greater than 15 points at 24 months compared to the score at baseline. Based on these alternat criteria, the overall success rate for subjects receiving the Charite Artificial Disc was 58%, and the success rate for control subjects was 54%.

The study sponsor considered the study a success if the overall success rates of the two treatment groups were no inferior, i.e., the difference in overall success rates (i.e., non-inferiority margin) is no greater than 15 %. However, the FDA requested that the data also be analyzed and reported using a non-inferiority margin of 10 %.

The study demonstrated non-inferiority of the Charite Artificial Disc (within the 90 % 1-sided confidence interval) to interbody fusion for secondary endpoints, including pain (using a visual analog scale (VAS)), quality of life (Shoft Form-36 Questionnaire), disc height, and device migration.

At 24 months follow-up, subjects receiving the Charite Artificial Disc had 7.5 degrees vertebral range of motion (ROM) at the operative level, compared to 1.1 degrees vertebral ROM for subjects receiving interbody fusion. Th FDA analyzed ROM data versus Overall Success Outcome for all Charite artificial disc subjects with available ROM data at 24 months. No statistically significant association was found between ROM and success/failure at 24 months.

Because the long-term safety and effectiveness of the Charite Artificial Disc are unknown, the FDA has required th manufacturer to conduct a post-approval study using a maximum of 366 subjects (201 randomized investigational subjects; 67 training investigational subjects; and 98 control subjects). The manufacturer will be required evaluate subjects on Overall Success and secondary endpoints, and submit annual reports for a total of 5 years post-implantation.

According to the FDA-approved labeling, the Charite Artificial Disc should not be implanted in patients with the following conditions: osteoporosis; osteopenia; pars defect; bony lumbar stenosis; active systemic infection or infection localized to the site of implantation; allergy or sensitivity to implant materials; and isolated radicular compression syndromes, especially due to disc herniation.

The FDA-approved labeling of the Charite Artificial Disc states that the safety and effectiveness of the device have not been established in patients with the following conditions: pregnancy; morbid obesity; two or more degenerative discs; spondylolisthesis greater than 3 mm; or two or more unstable segments.

Data on the long-term outcomes of the Charite Artificial Disc comes from France, where the artificial disc has been use for more than a decade. David (2000) reported in abstract form on a retrospective review of the outcome of 92 patients with chronic low back pain who were implanted with the artificial disc. The investigators reported “excellence or good” results in 75% of patients after a minimum of 5 years follow up, with no disc space height loss and no loosening or expulsion of the core. Lemaire, et al., described their 5-year and 10-year results with the Charite Artificial Disc. In the paper reporting on 10-year results, Lemaire, et al. (2002) reported an excellent or good
outcome in 90% of 100 patients with a return to work rate of 91.6%. In addition, the investigators reported no subluxations or core expulsions, a reoperation rate of 5% and a 2% rate of adjacent-level disc disease. The mean flexion/extension range of motion was 10.3 degrees, with a mean lateral bending motion of 5.4 degrees.

The National Institute for Clinical Excellence (2004) has concluded: “Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement appears adequate to support the use of this procedure. However, there little evidence on outcomes beyond 2-3 years and collection of long-term data is therefore particularly important”.

An assessment by the Ohio Bureau of Workers’ Compensation (2005) concluded that the Charite artificial disc can be considered as an alternative to tradition lumbar fusion procedures.

The Ontario Health Technology Advisory Committee of the Ontario Ministry of Health and Long-Term Care (2006) recommended the adoption of lumbar artificial disc replacement according to well defined patient eligibility criteria. The Ontario Health Technology Advisory Committee recommended development of a patient registry to track long-term complications of lumbar artificial disc replacement. Because of the uncertainty in the estimates of benefits, risks and burdens associated with cervical artificial disc replacement, the Ontario Health Technology Advisory Committee did not recommend the use of cervical artificial disc replacement to treat degenerative disc disease of the cervical spine over the use of other alternatives such as spinal fusion.

Tropiano et al (2005) presented the clinical and radiographic results assessed 7 to 11 years following a Prodisc total lumbar disc replacement (n = 64 patients who had single or multiple-level implantation of a total lumbar disc replacement). The mean duration of follow-up was 8.7 years. Clinical results were evaluated by assessing pre-operative and post-operative lumbar pain, radiculopathy, disability, and modified Stauffer-Coventry scores. Pre-operative and post-operative radiographs were evaluated as well. These investigators concluded that the Prodisc lumbar total disc replacement appears to be effective and safe for the treatment of symptomatic degenerative disc disease. Gender and multi-level surgery did not affect the outcomes, whereas prior lumbar surgery or an age of less than 45 years was associated with slightly worse outcomes. The authors further stated that longer follow-up of this cohort of patients and randomized trials comparing disc replacement with arthrodesis are needed.

Leivseth et al (2006) presented their findings of a longitudinal prospective study on the use of the ProDisc II prosthesis in 41 consecutive disc prosthesis patients, covering a post-operative time period of at least 2 years. The stated that disc replacement in the lumbar spine by a ProDisc II implant failed to restore normal segmental rotation motion in the sagittal plane, specifically at levels L4-L5 and L5-S1. As segmental motion of the untreated segments was lower than normal as well, though not quite as conspicuous as that of instrumented segments, adaptation of soft tissue taken place during the pre-operative symptomatic time period is conjectured to cause the observed motion deficit.

On the other hand, findings from other studies indicated that the ProDisc is safe and effective in treating patients with low back pain (LBP).

In a prospective, longitudinal minimum 2-year follow-up study (n = 118), Bertagnoli et al (2005) evaluated the safety and effectiveness of the ProDisc implant in patients with disabling single-level discogenic LBP. Patients 18 to 60 years of age with disabling and recalcitrant discogenic LBP with or without radicular pain secondary to single-level discogenic LBP from L3 to S1 were included. Patients were assessed before surgery, and outcome measurements were assessed after surgery at 3, 6, 12, and 24 months. A total of 104 patients (88%) fulfilled all follow-up criteria. The median age of all patients was 47 years (range of 36 to 60 years). Statistical improvements in VAS, Oswestry, and patient satisfaction scores occurred 3 months post-operatively. These improvements were maintained at the 2 month follow-up. Radicular pain also decreased significantly. Full-time and part-time work rates increased from 10 to 35% and from 3 to 24%, respectively. No additional fusion surgeries were needed either at the affected or unaffected levels. Radiographical analysis revealed an affected disc height increase from 4 to 13 mm (p < 0.001) and an affected disc motion from 3 to 7 degrees (p < 0.004). The authors concluded that single-level ProDisc lumbar total disc arthroplasty is a safe and effective treatment for debilitating lumbar discogenic LBP. Significant improvements

http://qawww.aetna.com/cpb/medical/data/500_599/0591_draft.html
patient satisfaction as well as disability scores occurred after surgery by 3 months and were maintained at the 2-ye
follow-up. No device-related complications occurred. Patients with severe to moderate disc height loss as well as
those with symptomatic posterior annular defects with minimal disc height loss achieve functional gains and
significant pain relief. Careful and appropriate patient selection is essential in ensuring optimal surgical outcomes.

Siepe et al (2006) presented their 3-year results with total lumbar disc replacement (TLDR) by means of the ProDi II
with a minimum follow-up of 24 months. They concluded that available data suggest beneficial clinical results of
TLDR for the treatment of DDD in a highly selected group of patients. Better functional outcome was obtained in
younger patients under 40 years of age and patients with DDD in association with disc herniation. Multi-level disc
replacement had significantly higher complication rate and inferior outcome at mid-term follow-up compared with
mono-segmental interventions. Thus, only longer follow-up evaluations will demonstrate the real benefit for patients
Results are significantly dependent on pre-operative diagnosis and patient selection, number of replaced segment
and age of patient at the time of operation. The authors stated that because of significantly varying outcomes,
indications for disc replacement must be defined precisely.

Schroven and Dorohey (2006) conducted a prospective, non-randomised study on the ProDisc IVD (n = 14) versus
anterior lumbar interbody fusion (ALIF, n = 10). In the ProDisc group, the Oswestry Disability Index improved from
38.42 pre-operatively (60 being the worst possible condition) to +/- 15.21 after 6 months, and to +/- 12.5 after 12
months. This was markedly better than the ALIF group, where the corresponding figures were +/- 38, +/- 25 and +/-
21.4. The ProDisc patients also scored better with respect to duration of hospitalization, blood loss and operation
time. The complications were comparable in both groups.

Tropiano and colleagues (2006) presented the clinical and radiographical results assessed 7 to 11 years following
ProDisc TLDR. A total of 64 patients had single- or multiple-level implantation of a TLDR between 1990 and 1993.
The mean duration of follow-up was 8.7 years. Clinical results were evaluated by assessing pre-operative and post
operative lumbar pain, radiculopathy, disability, and modified Stauffer-Coventry scores. Pre-operative and post-
operative radiographs were evaluated as well. Subgroup analysis was performed to determine if gender, an age of
less than 45 years, previous surgery, or multi-level surgery had an effect on outcome. At an average of 8.7 years
post-operatively, there were significant improvements in the back pain, radiculopathy, disability, and modified
Stauffer-Coventry scores. Thirty-three of the 55 patients with sufficient follow-up had an excellent result, 8 had a
good result, and 14 had a poor result. Neither gender nor multi-level surgery affected outcome. An age of less than
45 years and prior lumbar surgery had small but significant negative effects on outcome. Radiographs did not
demonstrate loosening, migration, or mechanical failure in any patient. Five patients had approach-related
complications. These investigators concluded that the ProDisc TLDR appears to be effective and safe for the
treatment of symptomatic DDD. Gender and multi-level surgery did not affect the outcomes, whereas prior lumbar
surgery or an age of less than 45 years was associated with slightly worse outcomes. The authors noted that long
follow-up of this cohort of patients and randomized studies comparing disc replacement with arthrodesis are neede

Bertagnoli and colleagues (2006a) conducted a prospective, longitudinal study (n = 20) to evaluate the effectiveve
of ProDisc arthroplasty in patients in whom symptomatic adjacent-segment degeneration has developed after remo
lumbar fusion. The follow-up period was a minimum of 2 years. Subjects in this study ranged in age from 18 to 67
years. They presented with disabling adjacent-level discogenic LBP with or without L1 - S1 radicular pain. Individu
with radiographic evidence of circumferential spinal stenosis or facet joint degeneration were excluded. Patients
were assessed pre-operatively and post-operatively at 3, 6, 12, and 24 months. Eighteen patients (90%) fulfilled al
follow-up criteria. The median age of all patients was 50 years. Statistical improvements in VAS, Oswestry Disabilit
Index, and patient satisfaction scores were documented 3 months after arthroplasty. These improvements remaine
at the 24-month follow-up examinations. Patient satisfaction rates were 86% at 24 months. Radicular pain was also
significantly decreased. No additional surgeries were needed at affected or unaffacted levels. The authors conclude
that analysis of early results indicates that ProDisc lumbar total disc arthroplasty is an effective treatment for
symptomatic adjacent-segment lumbar discogenic LBP following remote fusion. Significant improvements in patien
satisfaction and disability scores were observed by 3 months post-operatively and were maintained at the 2-year
follow-up examination. No device-related complications occurred. Patients should be screened carefully for evidence of facet joint impingement/degeneration, hardware-induced pain, and/or non-union at prior fusion levels before undergoing disc replacement surgery.

The same group of investigators (Bertagnoli et al, 2006b) also carried out a prospective, longitudinal study to obtain outcome (minimum follow-up period 2 years) regarding the safety and effectiveness of single-level lumbar disc replacement in patients 60 years of age or older. This analysis involved 22 patients in whom the ProDisc was used for total disc arthroplasty. All patients presented with disabling discogenic LBP with or without radicular pain. The involved segments ranged from L2 to S1. Patients in whom there was no evidence of radiographic circumferential spinal stenosis and with minimal or no facet joint degeneration were included. Patients were assessed pre-operatively and outcome was evaluated post-operatively at 3, 6, 12, and 24 months by administration of standardized tests (VAS, ODI, and patient satisfaction). Secondary parameters included analysis of pre- and post-operative radiographic results of disc height at the affected level, adjacent-level disc height and motion, and complications. Twenty-two subjects (100%) fulfilled all follow-up criteria. The median age of all patients was 63 years (range of 61 to 71 years). There were 17 single-level cases, 4 two-level cases, and 1 three-level case. Statistical improvements in VAS, ODI, and patient satisfaction scores were observed at 3 months post-operatively. These improvements were maintained at 24-month follow-up examination. Patient satisfaction rates were 94% at 24 months (compared with 95% reported in a previously reported ProDisc study). Radicular pain also decreased significantly. Patients in whom bone mineral density was decreased underwent same-session vertebroplasty following implantation of the ProDisc device(s). There were 2 cases involving neurological deterioration: unilateral foot drop and loss of proprioception and vibration in 1 patient and unilateral foot drop in another patient. Both deficits occurred in patients in whom there was evidence pre-operatively of circumferential spinal stenosis. There were 2 cases of implant subsidence and no thrombo-embolic phenomena. These researchers concluded that significant improvements in patient satisfaction and ODI scores were observed by 3 months post-operatively and these improvements were maintained at the 2-year follow-up examination. Although the authors' early results indicate that the use of ProDisc lumbar total disc arthroplasty in patients older than 60 years of age reduces chronic LBP and improves clinical functional outcomes, they recommend the judicious use of artificial disc replacement in this age group. Until further findings are reported, the authors cautiously recommend the use of artificial disc replacement in patients older than 60 years in whom bone quality is adequate in the absence of circumferential spinal stenosis.

Bertagnoli and associates (2006c) reported that lumbar total disc arthroplasty utilizing the ProDisc prosthesis is equally effective in smokers and non-smokers. These investigators performed a prospective analysis on 104 patients with disabling discogenic LBP treated with single-level lumbar ProDisc total disc arthroplasty. Smokers and non-smokers were evaluated before surgery and after surgery using patient satisfaction, Oswestry, and VAS. Additionally, pre-operative and post-operative neurological, radiographical, and pain medication assessments were performed at similar post-operative intervals. Oswestry, VAS, and patient satisfaction scores revealed statistical improvement beginning 3 months after surgery and were maintained at minimum 2-year follow-up. Patient satisfaction scores were higher in smokers (94%) than in non-smokers (87%) at 2-year follow-up (p = 0.07). Radiographical analysis revealed an affected disc height increase from 4 to 13 mm (p < 0.05) and an affected disc motion from 3 to 7 degrees (p < 0.05). No cases of loosening, dislodgment, mechanical failure, infection, or fusion of the affected segment occurred. The authors concluded that the findings of this study indicate that smokers do equally well as non-smokers when ProDisc artificial disc replacement is used in the treatment of debilitating lumbar spondylolisthesis. Patient outcome and radiographical scores showed significant improvement compared with pre-operative levels.

On August 14, 2006, the FDA approved the ProDisc-L Total Disc Replacement (Synthes Spine, Inc., West Chester PA) for spinal arthroplasty in patients who meet all of the following criteria:

Patients are skeletally mature; and
Patients have DDD at one level in the lumbar spine (from L3 to S1); and
Patients have no more than Grade 1 spondylolisthesis at the involved level; and
Patients have had no relief from pain after at least 6 months of non-surgical treatment.

Hannibal et al (2007) examined if there is a clinical difference between the 1-level ProDisc patients versus the 2-lev ProDisc patients at a minimum of 2-year follow-up. Patients were part of the FDA clinical trial for the Prodisc II versus circumferential fusion study at a single institution. These investigators identified 27 patients who received ProDisc a 1 level and 32 who received it at 2 levels with at least a 2-year follow-up, for a total of 59 patients. Unpaired t tests were performed on the mean results of VAS, ODI, 36-Item Short Form Health Survey (SF-36) Healthy Survey Physical Component Summary, and satisfaction using 10-cm line VAS to determine a clinical difference, if any, between the 2 populations. While patients receiving ProDisc at 2 levels scored marginally lower in all evaluation indexes, score differences in each category were also found to hold no statistical significance. The authors concluded that this study was unable to identify a statistically significant difference in outcome between 1- and 2-level ProDisc arthroplasty patients in a cohort from a single center. They stated that the equality of clinical effectiveness between 1- and 2-level ProDisc has yet to be determined.

In August 2007, the Centers for Medicare & Medicaid Services (CMS) concluded that lumbar artificial disc replacement (LADR) is not reasonable and necessary for the Medicare population over 60 years of age. CMS announced that Section 150.1 of the Medicare National Coverage Determination (NCD) Manual will be amended to reflect the proposed change from non-coverage for a specific LADR implant to non-coverage for the LADR procedure for the Medicare population over 60 years of age. For Medicare beneficiaries 60 years of age and under there is no national coverage determination, leaving such determinations to be made on a local basis.

An interventional procedure consultation document prepared for the National Institute for Health and Clinical Excellence (NICE, 2008) included the following provisional recommendations: "[c]urrent evidence on the safety an efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. A multi-disciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated. The current evidence is based on studies with maximum follow-up of 13 years. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery."

Acosta and Ames (2005) noted that cervical disc arthroplasty is a relatively new motion-preserving technique for the treatment of symptomatic DDD of the cervical spine. Unlike anterior disectomy and fusion, cervical disc replacement restores normal motion and a physiologic biomechanical environment to adjacent disc levels, thereby reducing the incidence of adjacent segment disease. To date, cervical disc arthroplasty has been at least as effective as cervical fusion in providing symptomatic relief while lowering peri-operative morbidity, eliminating the need for post-operative external immobilization, and allowing for earlier return to normal function. No significant complications have been associated with this procedure so far. The authors stated that further investigation in the form of large, randomized, prospective studies is needed to ascertain the long-term effectiveness of this procedure as well as to determine the patient populations that may benefit most from cervical disc arthroplasty. This is in agreement with the observations of Praczyk and Traynelis (2005) and Bertagnoli, et al. (2005). Praczyk and Traynelis stated that cervical arthroplasty (by means of devices such as Prestige, Bryan, and ProDisc) is a promising new technology that may improve patient outcome following anterior cervical decompression. Bertagnoli et al noted that long-term follow-up studies are needed before more definitive treatment recommendations can be made regarding cervical disc replacement by means of the ProDisc. Furthermore, in a review on the state of the emerging field of cervical disc replacement, Phillips and Garfin (2005) stated that cervical disc replacement is an innovative technology that preserves motion at the instrumented level/s, and will potentially improve load transfer to the adjacent levels compared with fusion. Clinical reports of success of cervical total disc replacement are encouraging but are also
quite preliminary. As the United States investigational device exemption studies are completed, a clearer role for the place of cervical disc replacement in the spine surgeon’s armamentarium should emerge.

Traynells and Treharne (2007) noted that the Prestige artificial cervical disc is a new motion-sparing device design for use in the cervical spine to treat symptomatic degenerative disc disease in patients who have failed conservative care. It allows for the maintenance of normal cervical spinal motion. Furthermore, this new device does not require bone graft or as long a recovery time as needed for fusion of the joint.

In a prospective, randomized, controlled and double-blinded study, Sekhon and colleagues (2007) compared post-operative imaging characteristics of the four currently available cervical arthroplasty devices (Bryan, Prodisc-C, Prestige LP, and PCM) at the level of implantation and at adjacent levels. Pre-operative and post-operative magnetic resonance imaging scans of 20 patients who had undergone cervical arthroplasty were evaluated for imaging quality. Five cases each of the four devices were analyzed. Six blinded spinal surgeons scored twice sagittal and axial T2-weighted images using the Jarvik 4-point scale. Statistical analysis was performed comparing quality before surgery and after disc implantation at the operated and adjacent levels and between implant types. Moderate intra-observer and inter-observer reliability was noted. Pre-operative images of patients in all implant groups had high-quality images at operative and adjacent levels. The Bryan and Prestige LP devices allowed satisfactory visualization of the canal, exit foramina, cord, and adjacent levels after arthroplasty. Visualization was significantly impaired in all PCM and Prodisc-C cases at the operated level in both the spinal canal and neural foramina. At the adjacent levels, image quality was statistically poorer in the PCM and Prodisc-C than those of Prestige LP or Bryan. The authors concluded that post-operative visualization of neural structures and adjacent levels after cervical arthroplasty is variable among current available devices. Devices containing non-titanium metals (cobalt-chrome-molybdenum alloys in the PCM and Prodisc-C) prevent accurate post-operative assessment with magnetic resonance imaging at the surgical and adjacent levels. On the other hand, titanium devices, with or without polyethylene (Bryan disc or Prestige LP), allow for satisfactory monitoring of the adjacent and operated levels. This information is crucial for any surgeon who wishes to assess adequacy of neural decompression and where monitoring of adjacent levels is desired.

Mummaneni and associates (2007) reported the results of a prospective randomized multi-center study in which the results of cervical disc arthroplasty with the Prestige ST Cervical Disc System (Medtronic Sofamor Danek) were compared with anterior cervical discectomy and fusion (ACDF). Patients with symptomatic (neck pain) single-level cervical DDD who failed at least 6 weeks of conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care were included in the study. Degenerative disc disease was determined to be present if a herniated disc and/or osteophyte formation were confirmed by history and radiograph studies (e.g., CT, MRI, x-rays). A total of 541 patients were enrolled at 32 sites and randomly assigned to 1 of 2 treatment groups: (i) 276 patients in the investigational group underwent anterior cervical discectomy and decompression and arthroplasty with the Prestige ST Cervical Disc System; and (ii) 265 patients in the control group underwent decompressive ACDF. A total of 80% of the arthroplasty-treated patients (223 of 276) and 75% of the control patients (198 of 265) completed clinical and radiographical follow-up examinations at routine intervals for 2 years after surgery. Analysis of all currently available post-operative 12- and 24-month data indicated a 2-point greater improvement in the neck disability index score in the investigational group than the control group. The arthroplasty group also had a statistically significant higher rate of neurological success (p = 0.005) as well as a lower rate of secondary revision surgeries (p = 0.0277) and supplemental fixation (p = 0.0031). The mean improvement in the 36-Item Short Form Health Survey Physical Component Summary scores was greater in the investigational group at 12 and 24 months, as was relief of neck pain. The patients in the investigational group returned to work 16 days sooner than those in the control group, and the rate of adjacent-segment re-operation was significantly lower in the investigational group as well (p = 0.0492, log-rank test). The cervical disc implant maintained segmental sagittal angular motion averaging more than 7 degrees. In the investigational group, there were no cases of implant failure or migration. The authors concluded that the Prestige Cervical Disc maintained physiological segmental motion at 24 months after implantation and was associated with improved neurological success, improved clinical outcomes, and a reduced rate of secondary surgeries compared with ACDF.
On July 17, 2007, the FDA approved the Prestige Cervical Disc (Medtronic Sofamor Danek, Memphis, TN) for the treatment of single level cervical degenerative disc disease (C3 to C7). The FDA approval was based on the finding of the study by Mummaneni, et al. (2007). In the approval letter, the FDA stated that Medtronic Sofamor Danek is required to perform a 7-year post-approval study to evaluate the long-term safety and effectiveness of the Prestige Cervical Disc.

Sasso et al (2007) evaluated the functional outcome and radiographical results of the Bryan artificial cervical disc replacement for patients with 1-level cervical disc disease. Twelve-month follow-up was available for 110 patients and 24-month follow-up was completed for 99 patients. There were 30 males and 26 females in the Bryan group and 32 males and 27 females in the fusion group. The average age was 43 years (Bryan) and 46 years (fusion). Disability and pain were assessed using the Neck Disability Index (NDI) and the VAS of the neck and of the arm pain. SF-36 outcome measures were obtained including the physical component as well as the mental component scores. Range of motion was determined by independent radiological assessment of flexion-extension radiographs. The average operative time for the control group was 1.1 hours and the Bryan Group 1.7 hours. Average blood loss was 49 ml (control) and 64 ml (Bryan). Average hospital stay was 0.6 days (control) and 0.9 days (Bryan). The mean NDI before surgery was not statistically different between groups: 47 (Bryan) and 49 (control). Twelve-month follow-up NDI is 10 (Bryan) and 18 (control) (p = 0.013). At 2-year follow-up, NDI for the Bryan group is 11 and the control group is 20 (p = 0.005). The mean arm pain VAS before surgery was 70 (Bryan) and 71 (control). At 1-year follow-up, Bryan arm pain VAS was 12 and control 23 (p = 0.031). At 2-year follow-up, the average arm pain VAS for the Bryan group was 14 and control 28 (p = 0.014). The mean neck pain VAS before surgery was 72 (Bryan) and 73 (control); 1-year follow-up scores were 17 (Bryan) and 28 (control) (p = 0.05); 2-year follow-up: 16 (Bryan) and 32 (control) (p = 0.005). SF-36 scores: Physical component -- before surgery Bryan 34 and control 32; at 24 months: Bryan 51 and control 46 (p = 0.009). More motion was retained after surgery in the disc replacement group than in the control group at the index level (p < 0.006 at 3, 6, 12, and 24 months). The disc replacement group retained an average of 7.9 degrees of flexion-extension at 24 months. In contrast, the average range of motion in the fusion group was 0.6 degrees at 24 months. There were 6 additional operations in this series: 4 in the control group and 2 in the investigational group. There were no intra-operative complications, no vascular or neurological complications, no spontaneous fusions, and no device failures or explantations in the Bryan cohort. The authors concluded that the Bryan artificial disc replacement compared favorably to anterior cervical discectomy and fusion for the treatment of patients with 1-level cervical disc disease. At the 2-year follow-up, there are statistically significant differences between the groups with improvements in the NDI, the neck pain and arm pain VAS scores, and the SF-36 physical component score in the Bryan disc population.

In December 2007, the FDA approved the ProDisc-C Total Disc Replacement (Synthes Spine, Inc., West Chester, PA) for use in skeletally mature patients for reconstruction of the disc from C3-C7 following removal of the disc at one level for intractable symptomatic cervical disc disease (SCDD). The FDA's approval of the ProDisc-C was based upon the results of a clinical trial (non-inferiority) involving 209 patients at 13 clinical sites comparing ProDisc C to ACDF. Patients with SCDD who failed at least 6 weeks of non-operative treatment or had progressive symptoms or signs of nerve root/spinal cord compression in the face of conservative treatment qualified for the trial. Intractable SCDD was defined as neck or arm (radicular) pain, and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or x-rays): (i) herniated nucleus pulposus, (ii) spondylosis (defined by the presence of osteophytes), or (iii) loss of disc height. Patients were evaluated for pain and disability, neurologic status and range of motion at the index level. Patients were followed for 2 years post surgery. The study data indicated that the ProDisc-C is non-inferior to ACDF. According to the FDA-approved labeling, the ProDisc-C should not be implanted in patients with an active infection, allergy to any of the device materials, osteoporosis, marked cervical instability, severe spondylosis, clinically compromised vertebral bodies at the level to be treated, and SCDD at more than one level. The device is implanted via an open anterior approach.

In December 2009, the FDA approved the Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, TN) for use in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable
radiculopathy and/or myelopathy. The FDA's approval of the Bryan Cervical Disc was based upon the results of a clinical trial (non-inferiority) involving 463 patients at 30 clinical sites comparing the Bryan device to ACDF. Patient with intractable radiculopathy and/or myelopathy resulting in impaired function with at least one clinical neurologica sign associated with the cerebral level to be treated and who failed at least 6-weeks of conservative treatment qualified for the trial. Intractable radiculopathy and/or myelopathy was defined as any combination of the following conditions confirmed by imaging (computed tomography, myelography and computed tomography, and/or magneti resonance imaging): (i) disc herniation with radiculopathy, (ii) spondylotic radiculopathy, (iii) disc herniation with myelopathy, or (iv) spondylotic myelopathy. Patients were evaluated for pain and disability, and neurological status Patients were followed for 2 years post surgery. The study data indicated that the Bryan Cervical Disc is non-infer to ACDF. According to the FDA-approved labeling, the Bryan Cervical Disc should not be implanted in patients wit an active infection, allergy to any of the device materials, osteoporosis, moderate to advanced spondylitis, marke cervical instability, significant cervical anatomical deformity or compromised vertebral bodies at the index level, significant kyphotic deformity or significant reversal of lordosis, or symptoms necessitating surgical treatment at mo than one cervical level. The Bryan device is implanted via an open anterior approach. Because the specific polyurethanes used in the device have not be exhaustively studied for use as sheaths or nuclei in a cervical disc prosthesis, the FDA recommended that the sponsor continue to evaluate explanted devices in a 10 year post-approval study.

An assessment by the BlueCross BlueShield Association Technology Evaluation Center (2009) found that artificial intervertebral disc arthroplasty for the treatment of patients with cervical DDD does not meet its criteria for improvin net health outcomes or is as beneficial as ACDF.

A draft assessment by the California Technology Assessment Forum (2009) found insufficient evidence that cervic disc replacement for patients with cervical DDD improves health outcomes over the long term.

Lumbar partial disc replacement is a minimally invasive procedure that replaces only the nucleus pulposus in an attempt to fill the therapy gap between discectomy and fusion. The procedure targets only the nucleus pulposus as the origin of pain while attempting to restore the biomechanical function of the whole segment. Careful patient selection is crucial since the prosthetic nucleus is not fixed into position. An intact annulus and properly functionin endplates must be present. Exclusion criteria include osteoporosis, endplate problems, posterior element disorder (e.g., stenosis, facet arthritis, isthmic pathologies), and infection tumors. There are several lumbar partial disc replacement devices currently under investigation. These devices use hydrogel, polymer/synthetic, or mechanical technologies, however, none are commercially available in the United States. All non-fusion spinal implants are considered Class III medical devices and require Pre-Market Approval (PMA) from the FDA prior to market release the United States.

Nubac (Pioneer Surgical Technology, Inc., Marquette, MI) is an elastomeric nucleus replacement device composed of polyetheretherketone (PEEK) that is used in partial disc replacement. The Nubac procedure is intended to conserve most of the annular tissue and to be less invasive than total disc replacement and fusion allowing further treatment options if revision is required. Alpizar-Aguirre, et al. (2008) reported the results of 10 patients with DDD who underwent discectomy with the Nubac device. Surgical approach was anterolateral (n = 4), posterior (n = 3) a anterior (n = 3). After 3-months post-operatively, ODI improved from 58.2% to 24.2% (p < 0.05), VAS improved fro 8.1 to 2.5 (p < 0.05), and disc height improved from 9.4 mm to 12.5 mm, but lumbar motion did not improve. The authors concluded that the Nubac prosthesis improved lumbar discogenic pain in a short time, however, a minimu follow-up of 4 years is needed to make a definite conclusion. According to a review of nucleus replacement technologies (Coric & Mummaneni, 2008), a challenge of using preformed elastomeric devices is implant extrusion due to their inherently deformable nature. Other issues include their durability and their effectiveness compared to established alternatives (e.g., laminectomy, percutaneous diskektomy) for lumbar disc herniation. Available published peer reviewed evidence of the Nubac disc prosthesis is of a preliminary nature. Well controlled clinical studies are necessary to evaluate the effectiveness, safety and durability of results of this device.
The DASCOR (Disc Dynamics Inc., Eden Prairie, MN) is a balloon device that is inserted into the disc space after total nucleus removal. The balloon is then filled with an injectable polyurethane polymer that conforms to the individual's anatomy. The remaining implant is designed to restore the original disc function and replaces the nucleus. Ahrens, et al. (2009) reported the results from 2 prospective, non-randomized multi-center European studies on lumbar disc nucleus replacement using the DASCOR disc arthroplasty device for DDD ($n = 85$). Data were collected before surgery and after surgery at 6 weeks and at 3, 6, 12, and 24 months. The clinical outcome measures were obtained fromVAS for back pain, ODI, radiographic assessments, and records of analgesic medication use. Mean VAS and ODI scores improved significantly after 6 weeks and throughout the 2 years. Radiographic results demonstrated, at a minimum, maintenance of disc height with no device expulsion and, despite Modic-Type 1 changes, no subsidence. Fourteen patients had serious adverse events including device explants in patients ($7 \text{ of } 85$), in which the main complication was resumed back pain after time. Patients' rate of analgesic medication decreased dramatically over time, with all patients experiencing significant improvements after 3 month and nearly no analgesic medication or narcotic drug use at 2 years. The authors concluded that these interim outcomes showed significant improvements in mean ODI and VAS scores and suggest that the DASCOR device may be a safe and effective less-invasive surgical option for patients with DDD.

Further clinical investigation with well-designed prospective, randomized trials is needed to determine the efficacy of nucleus replacement in the treatment of lumbar DDD, as well as its ideal indications.

Zigler and Delamarter (2012) evaluated the long-term safety and effectiveness of the ProDisc-L total disc replacement (TDR) as part of an FDA-mandated post-market approval study. This report summarized the clinical findings after 5 years of follow-up. A total of 236 patients were treated and followed-up for 5 years; 161 TDRs and 75 fusions had been performed in these patients. The primary outcome was a 10-component success end-point. Secondary outcome measures included neurological status, secondary surgery, ODI, SF-36, VAS assessing pain and satisfaction, radiographic data, narcotic use, activity, and recreation status. Patients were monitored through their 5-year post-operative visits under the FDA post-market surveillance provisions in the original investigational device exemption approval. The overall follow-up rate at 5 years was 81.8 %. Study success demonstrated that TDR was non-inferior to fusion with a 12.5 % margin ($p = 0.0099$). Both TDR and fusion treatment groups maintained significant improvement on the ODI at 5 years compared with baseline ($p < 0.0001$). Secondary surgeries at the index level were performed in 12 % of fusion patients and 8 % of TDR patients. Radiographically, none of the TDRs developed spontaneous fusion. The segmental ROM following TDR remained within normal range, although it decreased by approximately $0.5^\circ$ in years 3 to 5. The VAS pain scores decreased from pre-operative values by 48 % in both treatment groups at 5 years. Patient satisfaction remained high in both groups (7 %), while the percentage of patients indicating that they would have the surgery again was higher in TDR patients (82.5 %) than in fusion patients (68.0 %). The authors concluded that patients in both groups maintained significa improvement during the 5-year follow-up. The TDR group had significantly better improvement on some scales. Although TDR patients avoid the stiffness of fusion and are more satisfied than fusion patients, both fusion and TD are reasonable surgical options in this specific patient population.

Zigler and colleagues (2012) reported the 5-year results for radiographically demonstrated adjacent-level degenerative changes from a prospective multi-center study in which patients were randomized to either TDR or circumferential fusion for single-level lumbar DDD. A total of 236 patients with single-level lumbar DDD were enrolled and randomly assigned to 2 treatment groups: (i) 161 patients in the TDR group were treated using the ProDisc-L, and (ii) 75 patients were treated with circumferential fusion. Radiographic follow-up data 5 years after treatment were available for 123 TDR patients and 43 fusion patients. To characterize adjacent-level degeneratio (ALD), radiologists at an independent facility read the radiographic films. Adjacent-level degeneration was characterized by a composite score including disc height loss, endplate sclerosis, osteophytes, and spondylolisthesis. At 5 years, changes in ALD (ALDs) compared with the pre-operative assessment were reported. Changes in ALD at 5 years were observed in 9.2 % of TDR patients and 28.6 % of fusion patients ($p = 0.004$). Among the patients without adjacent-level disease pre-operatively, new findings of ALD at 5 years post-
treatment were apparent in only 6.7% of TDR patients and 23.8% of fusion patients (p = 0.008). Adjacent-level surgery leading to secondary surgery was reported for 1.9% of TDR patients and 4.0% of fusion patients (p = 0.6819). The TDR patients had a mean pre-operative index-level ROM of 7.3° that decreased slightly (to 6.0°) at years after treatment (p = 0.0198). Neither treatment group had significant changes in either ROM or translation at the superior adjacent level at 5 years post-treatment compared with baseline. The authors concluded that at 5 years after the index surgery, ProDisc-L maintained ROM and was associated with a significantly lower rate of ΔALDs than in the patients treated with circumferential fusion. In fact, the fusion patients were greater than 3 times more likely experience ΔALDs than were the TDR patients.

It is interesting to note that a Cochrane review on “Total disc replacement for chronic back pain” (Jacobs et al, 201) concluded that “Although statistically significant, the differences between disc replacement and conventional fusion surgery for degenerative disc disease were not beyond the generally accepted clinical important differences with respect to short-term pain relief, disability and Quality of Life. Moreover, these analyses only represent a highly selected population. The primary goal of prevention of adjacent level disease and facet joint degeneration by using total disc replacement, as noted by the manufacturers and distributors, was not properly assessed and not a research question at all. Unfortunately, evidence from observational studies could not be used because of the high risk of bias, while these could have improved external validity assessment of complications in less selected patient groups. Non-randomized studies should however be very clear about patient selection and should incorporate independent, blinded outcome assessment, which was not the case in the excluded studies. Therefore, because believe that harm and complications may occur after years, we believe that the spine surgery community should be prudent about adopting this technology on a large scale, despite the fact that total disc replacement seems to be effective in treating low-back pain in selected patients, and in the short term is at least equivalent to fusion surgery.

In addition, a BlueCross BlueShield TEC assessment on “Artificial lumbar disc arthroplasty for treatment of degenerative disc disease of the lumbar spine” (2013) commented on the 5-year follow-up studies by Ziegler and colleagues (2012). The TEC assessment stated that “The manufacturer of ProDisc continued a 24-month investigational device exemption non-inferiority (NI) clinical trial (d = 12.5 %) to obtain 5-year follow-up data. The continuation trial used the same primary composite endpoint (referred to as “success”) as the original clinical trial. This endpoint comprised the ODI, SF-36 Physical Component Score, neurological status, reoperations, and 6 radiographic criteria for fusion. To be deemed a “success”, a patient had to achieve all 10 endpoints of the composite measure. The proportion of patients reaching success in each group was compared using a 12.5 % NI margin. At 5 years follow-up, 53.7 % of ProDisc patients and 50.0 % of fusion patients achieved success, suggesting non-inferiority for ProDisc compared with fusion. However, this analysis was based on 75 % of the original ProDisc recipients and 85 % of fusion patients. An intent-to-treat analysis showed success was achieved in 53.3 % of ProDisc recipients and 47.3 % of fusion cases. An alternate analysis, using more conservative criteria requested by FDA (ODI minimum 15-point improvement for lower back pain and 10 % non-inferiority margin), showed 48.1 % of ProDisc recipients and 41.1 % of fusion patients achieved success at 5 years. The number of adverse events reported per patient did not differ between groups (5.4 for ProDisc versus 5.1 for fusion, p = 0.507) although unspecified severe or life-threatening adverse events were reported more commonly in fusion patients (0.58 per patient) than ProDisc recipients (0.38 per patient) (p = 0.036). This evidence is insufficient to demonstrate a relative clinical benefit of ProDisc versus fusion, particularly because the effectiveness of the comparator – fusion - versus non-surgical treatments is not well defined. Thus, the randomized trial of ProDisc is suspect as a valid no inferiority trial and does not prove superiority”.

Furthermore, an UpToDate review on “Subacute and chronic low back pain: Surgical treatment” (Chou, 2014) states that “Disc replacement is approved by the FDA for patients who are in good health, ≤ 60 years old, with disease limited to one disc between L3 and S1 and no associated deformity, spondylolisthesis, or neurologic deficit. Patients should be treated by surgeons experienced in performing disc replacement, to minimize complications and length of hospitalization. Guidelines from the American Pain Society found insufficient evidence regarding long-term benefit and harms of disc replacement to support recommendations …. Vertebral fusion is the most common surgery for chronic, nonspecific low back pain. Surgical instrumentation (use of pedicle screws or other hardware) increases
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fusion rates, but it is not known if instrumentation improves clinical outcomes. More research with longer follow-up needed to determine the appropriate role of artificial disc replacement versus fusion. We suggest that vertebral fusion be performed for patients who undergo surgical intervention for chronic low back pain”.

Quan et al (2011) evaluated the long-term outcome of cervical disc arthroplasty. A total of 21 patients underwent 2 total disc arthroplasties using the Bryan cervical disc after anterior cervical discectomy. Clinical and radiological data were obtained from the 8-year post-operative review. Nineteen of 21 patients were able to perform daily activities without limitation; 20 of 21 patients reported fair to excellent outcome according to Odom criteria and 21 of 27 (78 %) operated segments were mobile. Functional prostheses moved an average of 10.6°, which was similar to the range of movement of the adjacent non-operated segments of the cervical spine. Heterotopic ossification was evident in 13 of the 27 (48 %) operated segments and restricted movement of the prosthesis in 9 cases. Five of the 6 patients who received bivel arthroplasties developed heterotopic ossification. There was 1 case of posterior migration of the prosthesis, which did not have any clinical repercussion. No other case showed evidence of migration, subsidence, loosening, or wear. Radiological evidence of adjacent segment degeneration was observed in 4 patients (19 %); however, each of these patients had pre-existing degenerative disc disease at these levels on pre-operative imaging. The authors concluded that at 8-year follow-up, the Bryan cervical disc arthroplasty maintains favorable clinical and radiological results, with preservation of movement and satisfactory clinical outcome in the majority of cases. However, the incidence of heterotopic ossification causing restricted range of movement of the prosthesis appears to increase with time, especially in bivel procedures.

On September 28, 2012, the FDA approved the SECURE-C Artificial Cervical Disc, which is intended to be used in skeletally mature patients to replace a cervical disc (from C3 to C7) following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy or myelopathy) at only 1 level. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm322270.htm.

Contraindications of the Secure-C Artificial Cervical Disc:

- Active systemic infection or an infection at the operating site
- Allergy to the metals in the device (cobalt, chromium, molybdenum, or titanium), or to the type of plastic use in the device (polyethylene)
- Facet joint arthropathy
- More than 1 cervical disc requiring treatment (since device has only been evaluated in patients with one cervical disc requiring treatment)
- Osteoporosis or osteopenia
- Severe spondylosis
- Unstable cervical spine
- Weakened bones at the affected level due to current or past trauma

On August 23, 2013, the FDA approved the Mobi-C for 2-level cervical disease. However, pivotal clinical studies excluded patients with DJD at more than 1-level.

Beaurain and colleagues (2009) reported the intermediate results of an undergoing multi-center prospective study TDR with Mobi-C prosthesis. These researchers evaluated (i) the safety and effectiveness of the device in the treatment of DDD and (ii) the radiological status of adjacent levels and the occurrence of ossifications, at 2-year follow-up (FU). A total of 76 patients had performed their 2-year FU visit and had been analyzed clinically and radiologically. Clinical outcomes (NDI, VAS, SF-36) and ROM measurements were analyzed pre-operatively and the different post-operative time-points. Complications and re-operations were also assessed. Occurrences of heterotopic ossifications (HOs) and of adjacent disc degeneration radiographic changes have been analyzed from year FU X-rays. The mean NDI and VAS scores for arm and neck were reduced significantly at each post-operativ time-point compared to pre-operative condition. Motion was preserved over the time at index levels (mean ROM = degrees at 2 years) and 85.5 % of the segments were mobile at 2 years. Heterotopic ossifications were responsib
for the fusion of 6/76 levels at 2 years. However, presence of HO did not alter the clinical outcomes. The occurrence rate of radiological signs of ALD was very low at 2 years (9.1 %). There had been no subsidence, no expulsion and no sub-luxation of the implant. Finally, after 2 years, 91 % of the patients assumed that they would undergo the procedure again. The authors concluded that these intermediate results of TDR with Mobi-C were very encouraging and appeared to confirm the safety and effectiveness of the device. However, they noted that long-te studies are needed to fully evaluate the future of operated spine and the ability of arthroplasty with Mobi-C to provide the good answers to numerous questions asked by treatment of cervical DDD (e.g., the preservation of the status of the adjacent levels).

Huppert et al (2011) compared the safety and effectiveness of disc replacement with an unconstrained prosthesis multi- versus single-level patients. A total of 231 patients with cervical DDD who were treated with cervical disc replacement and completed their 24 months FU were analyzed prospectively: 175 were treated at 1-level, 56 at 2-level or more. Comparison between both groups was based on usual clinical and radiological outcomes (NDI, VA ROM, satisfaction). Safety assessments, including complication and subsequent surgeries, were also documented and compared. Mean NDI and VAS scores for neck and arm pain were improved in both groups similarly. Improvement of mobility at treated segments was also similar. Nevertheless, in the multi-level group, analgesic us was significantly higher; and occurrence of HOVs was significantly lower than in the single-level group. Subject satisfaction was nearly equal, as 94.2 % of single-level group patients would undergo the surgery again versus 94.6 % in the multi-level group. The overall success rate did not differ significantly. Multi-level DDD is a challenging indication in the cervical spine. This study showed no major significant clinical difference between the 2 groups. T authors concluded that there is a need for further studies to ascertain the impact of multi-level arthroplasty, especially on ALD, but these results demonstrated initial safety and effectiveness in this patient sample. The major drawbacks of this exploratory study were small sample size, lack of randomization, and the p values suggested a trend towards similar results in the outcomes of single-level versus multi-levels populations.

Davis et al (2013) compared the Mobi-C cervical artificial disc to ACDF for treatment of cervical DDD at 2 contiguous levels of the cervical spine. The primary clinical outcome was a composite measure of study success at 24 months. The comparative control treatment was ACDF using allograft bone and an anterior plate. A total of 330 patients we enrolled, randomized, and received study surgery. All patients were diagnosed with intractable symptomatic cervical DDD at 2 contiguous levels of the cervical spine between C3 and C7. Patients were randomized in a 2:1 ratio (TD patients to ACDF patients). A total of 225 patients received the Mobi-C TDR device and 105 patients received ACDF. At 24 months only 3.0 % of patients were lost to FU. On average, patients in both groups showed significa improvements in NDI score, VAS neck pain score, and VAS arm pain score from pre-operative baseline to each time-point. However, the TDR patients experienced significantly greater improvement than ACDF patients in NDI score at all time-points and significantly greater improvement in VAS neck pain score at 6 weeks, and at 3, 6, and 12 months post-operatively. On average, patients in the TDR group also maintained pre-operative segmental ROM at both treated segments immediately postoperatively and throughout the study period of 24 months. The re-operative rate was significantly higher in the ACDF group at 11.4 % compared with 3.1 % for the TDR group. Furthermore, a 24 months TDR demonstrated statistical superiority over ACDF based on overall study success rates. The authors concluded that the results of this study represented the first available Level I clinical evidence in support of cervical arthroplasty at 2 contiguous levels of the cervical spine using the Mobi-C cervical artificial disc. Moreover, they stated that additional rigorous research will further the understanding of the safety and effectiveness of multi-level cervical arthroplasty and arthrodesis procedures.

Coric et al (2013) evaluated the long-term results of cervical TDR and ACDF in the treatment of single-level cervic radiculopathy. The results of 2 separate prospective, randomized, FDA Investigational Device Exemption pivotal trials (Bryan Disc and Kinflex(C)) from a single investigational site were combined to evaluate outcomes at long-te FU. The primary clinical outcome measures included the NDI, VAS, and neurological examination. Patients were randomized to receive cervical TDR in 2 separate prospective, randomized studies using the Bryan Disc or Kinflex(C) cervical artificial disc compared with ACDF using structural allograft and an anterior plate. Patients were evaluated pre-operatively; at 6 weeks; at 3, 6, and 12 months; and then yearly for a minimum of 48 months. Plain
radiographs were obtained at each study visit. A total of 74 patients were enrolled and randomly assigned to either the cervical TDR (n = 41) or ACDF (n = 33) group. A total of 63 patients (86%) completed a minimum of 4 years FU. Average follow-up was 6 years (72 months) with a range from 48 to 108 months. In both the cervical TDR and ACDF groups, mean NDI scores improved significantly by 6 weeks after surgery and remained significantly improved throughout the minimum 48-month follow-up (p < 0.001). Similarly, the median VAS pain scores improved significantly by 6 weeks and remained significantly improved throughout the minimum 48-month follow-up (p < 0.001). There were no significant differences between groups in mean NDI or median VAS scores. The ROM in the cervical TDR group remained significantly greater than the pre-operative mean, whereas the ROM in the ACDF group was significantly reduced from the pre-operative mean. There was significantly greater ROM in the cervical TDR group compared with the ACDF group. There were 3 re-operations (7.3%) at index or adjacent levels in the cervical TDR group; all were cervical lamino-foraminotomies. There were 2 adjacent-level re-operations in the cervical TDR group (4.9%). There was 1 re-operation (3.0%) in the ACDF group at an index or adjacent level (a second ACDF at the adjacent level). There was no statistically significant difference in overall re-operation rate or adjacent-level re-operation rate between groups. The authors concluded that both cervical TDR and ACDF groups showed excellent clinical outcomes that were maintained over long-term FU. Both groups showed low index-level and adjacent-level re-operation rates. Both cervical TDR and ACDF appeared to be viable options for the treatment of single-level cervical radiculopathy.

Furthermore, in a systematic review on “Artificial cervical disc arthroplasty versus anterior cervical discectomy and fusion”, Bakar et al (2014) concluded that “Given the long-term outcomes that have been studied for anterior cervical discectomy and fusion, it is difficult to assess the future potential of anterior cervical disc arthroplasty as an alternative to anterior cervical discectomy and fusion. It is important to note that current studies with follow-up to 4 years have shown promising outcomes. The ability of anterior cervical disc arthroplasty to decrease the potential for common and well-known late complications of anterior cervical discectomy and fusion (such as adjacent segment disease) is an important and interesting possibility. Future long-term randomized controlled trials and cost effectiveness studies are needed to properly assess the continued use of artificial cervical disc arthroplasty and to determine the relative cost-effectiveness compared with anterior cervical discectomy and fusion”.

**CPT Codes / HCPCS Codes / ICD-9 Codes**

**CPT codes covered if selection criteria are met:**

22856

22861

**CPT codes not covered for indications listed in the CPB:**

+ 0092T

+ 0098T

+ 0163T

+ 0165T

22857

22862

**Other CPT codes related to the CPB:**
+ 0095T
+ 0164T
22533
22548
22551
+22552
22554
22558
22612
22630
22633
22634
22864
22865

**ICD-9 codes covered if selection criteria are met:**

722.0  Displacement of cervical intervertebral disc without myelopathy [one level]
722.4  Degeneration of cervical intervertebral disc [one level]
722.52 Degeneration of lumbar or lumbosacral intervertebral disc

**ICD-9 codes not covered for indications listed in the CPB:**

722.52 Degeneration of lumbar or lumbosacral intervertebral disc

**Other ICD-9 codes related to the CPB:**

278.01  Morbid obesity
630 - 679.14  Complications of pregnancy, childbirth, and the puerperium
724.6  Disorders of sacrum
738.4  Acquired spondylolisthesis
756.12  Spondylolisthesis
805.00 - 806.9 Fractures of vertebral column
V22.0 - V23.9 Supervision of pregnancy
The above policy is based on the following references:

23. Mundy L, Merlin T. Artificial invertebral disc or the replacement of degenerative lumbar or cervical discs in patients suffering disabling, chronic pain. Horizon Scanning Prioritising Summary - Volume 1. Adelaide, SA: Adelaide Health Technology Assessment (AHTA) on behalf of National Horizon Scanning Unit (HealthPACT and MSAC); 2003.


63. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus


