

Total Artificial Disc Replacement for the Spine (for Louisiana Only)

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[Instructions for Use](#)

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one-level or two contiguous levels of cervical Degenerative Disc Disease (C3 to C7), in a Skeletally Mature individual with symptomatic radiculopathy and/or myelopathy when the following criteria are met:

- Documented individual history of neck and/or upper extremity pain and/or a functional/neurological deficit associated with the cervical level to be treated
- Imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI]) confirming herniated nucleus pulposus or osteophyte formation
- Failed at least six weeks of non-operative treatment prior to implantation

Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent) is unproven and not medically necessary due to insufficient evidence of efficacy.

Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating single level lumbar Degenerative Disc Disease with symptomatic intractable discogenic low back pain in a Skeletally Mature individual when there are no [contraindications](#) and all of the following criteria are met:

- Advanced Degenerative Disc Disease (DDD) in only one vertebral level between L3 and S1 confirmed by complex imaging studies (i.e., computerized tomography [CT] scan or magnetic resonance imaging [MRI]) that indicate either moderate to severe Degenerative Disease or Modic Changes
- Symptoms correlate with imaging findings
- No more than Grade 1 Spondylolisthesis at the involved level or any listhesis at two or more lumbar segments
- Presence of symptoms for at least six months

- Failed at least 6 months of conservative treatment immediately prior to implantation of artificial disc; conservative treatment shall include all of the following, unless contraindicated: physical therapy, anti-inflammatory medications, analgesics, muscle relaxants, and epidural steroid injections
- Age 18 to 60 years
- Favorable psychosocial-behavioral evaluation to be conducted by an individual who is professionally recognized as part of a behavioral health discipline to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome

Contraindications to lumbar artificial total disc replacement include but are not limited to the following:

- Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph
- Lumbosacral spinal fracture
- Scoliosis of the lumbosacral spine
- Active systemic infection or infection localized to the site of implantation
- Tumor in the peritoneum, retroperitoneum or site of implantation
- Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan
- Isolated radicular compression syndromes especially due to disc herniation
- Spinal stenosis or radiculopathy
- Previous lumbar spine surgery where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain
- Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery

Lumbar artificial total disc replacement is unproven and not medically necessary in the following situations due to insufficient evidence of efficacy:

- More than one spinal level
- Prior history of lumbar fusion or when combined with a lumbar fusion at any level
- Treating any other indications not listed above

Definitions

Degenerative Disc Disease (DDD): Discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.

Grade 1 Spondylolisthesis: 25% of vertebral body has slipped forward.

Modic Changes: Peridiscal bone signal above and below the disc space in question.

Skeletally Mature: The apparent stage of development the bones of a growing child or adolescent. It is determined with radiological studies. The determination is used to analyze normal and disordered growth in children.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)

CPT Code	Description
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (List separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0375T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar

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Description of Services

Artificial total disc replacement refers to the replacement of a degenerating intervertebral disc with an artificial disc in adults with degenerative disc disease (DDD) in either the lumbar or cervical region of the spine. An artificial disc is intended to preserve range of motion (ROM) and reduce pain (ECRI, 2009). These prostheses replace the degenerated disc and have been proposed as a means of improving flexibility, maintaining spinal curvature and providing an equalized weight-bearing surface, while reducing or possibly eliminating pain.

Artificial discs may consist of two cobalt-chromium endplates that are attached to the vertebrae and a polyethylene disk that is inserted between the metal endplates may be metal on metal, metal on plastic, ceramic on ceramic or titanium on polyurethane. Discs are implanted through an anterior approach and are attached to vertebrae with screws, teeth, ridges, or pins.

Clinical Evidence

Cervical Artificial Disc (Single Level)

Latka et al. (2019) performed a meta-analysis to compare the safety and efficacy of cervical disc arthroplasty (CDA) to those of the gold standard, anterior cervical discectomy and fusion (ACDF). Both surgical and clinical parameters were employed to verify the hypothesis that CDA can reduce the risk of adjacent segment degeneration (ASD). Twenty randomized controlled trials studies with 3,656 patients (2,140 with CDA and 1,516 with ACDF) met the inclusion criteria. CDA surgery, with mean duration longer than that of ACDF, was associated with higher blood loss. Visual analog scale neck pain score was significantly smaller for CDA. The frequency of dysphagia/dysphonia as well as the long-term ASD rate for CDA was significantly smaller.

The authors concluded that a significantly lower probability of ASD reoperations in the CDA cohort after a 60-month or longer follow-up was the most important finding of this study. Despite the moderate quality of this evidence, the pooled data corroborated for the very first time that CDA was efficacious in preventing ASD.

Findlay et al. (2018) conducted a systematic review and meta-analysis to determine how the short- and medium- to long-term outcome measures after total disc replacement (TDR) compare with those of anterior cervical discectomy and fusion (ACDF). Inclusion criteria involved prospective randomized control trials (RCTs) reporting the surgical treatment of patients with symptomatic degenerative cervical disc disease. A total of 14 RCTs were included, representing 3160 patients with follow-up of up to ten years. Meta-analysis indicated that TDR is superior to ACDF at two years and between four and seven years. In the short-term, patients who underwent TDR had better patient-reported outcomes than those who underwent ACDF. Results between four and seven years showed significant differences in Neck Disability Index (NDI), 36-Item Short-Form Health Survey (SF-36) physical component scores, dysphagia, and satisfaction, all favoring TDR. Most trials found significantly less adjacent segment disease after TDR at both two years (short-term) and between four and seven years (medium- to long-term). The authors concluded that TDR is as effective as ACDF and superior for some outcomes. Disc replacement reduces the risk of adjacent segment disease.

A meta-analysis of published randomized controlled trials (RCTs) was conducted by Gutman et al. (2018) to determine whether anterior cervical discectomy and fusion (ACDF), cervical disc replacement (CDR), or minimally invasive posterior cervical foraminotomy (MI-PCF) provides the best outcomes for patients with symptomatic single-level, single-side, and cervical radiculopathy. Four RCT reports met the inclusion criteria for this study. Available data from the RCTs analyzed concluded that ACDF, CDR, and MI-PCF result in significant improvements in relevant symptoms, clinical, and functional outcomes in patients with single-level, single side cervical radiculopathy refractory to nonoperative treatment. CDR had the lowest percentage of secondary surgical procedures and MIPCF had the lowest percentage of adverse events. The authors concluded that all three techniques are effective in treating cervical radicular symptoms. There is insufficient evidence to show which technique is the most effective and provides the longest-lasting symptom relief.

A prospective study was performed by Pointillart et al. (2018) to assess the clinical and radiological results of Bryan cervical disc replacement at 15-year follow-up. The study included 20 patients who underwent cervical total disc replacement (CTDR), comprising a single-level procedure in 14 patients and two-level procedures in six patients. The mean follow-up period was 15.5 years. Two patients needed re-operation for recurrence of symptoms. According to Odom's criteria, 80.0% (16 of 20 patients) had excellent outcomes, VAS for neck pain was 2.6 (0-10), for shoulder/arm pain it was 1.8 (0-7), and NDI at the final follow up was 14.9. The SF-12 PCS was 46.1, and SF-12 MCS was 51.9. Mobility was maintained in 15 of the 22 (68.2%) operated segments, range of motion (ROM) of prostheses were $9^{\circ} \pm 3.9^{\circ}$ (range 4-15 $^{\circ}$). The prostheses were positioned in kyphosis in 14 of 22 levels (63.6%). There was a positive correlation between the kyphosis of the prosthesis and the occurrence of heterotopic ossification (HO), and their grade. HO had developed at 12 of the 22 levels (54.5%) and upper adjacent segment degeneration in 11 of 18 of patients (64.7%). All these results were not significantly different to outcomes at 8 years follow-up. The authors concluded that in a cohort of 20 patients with 15-year clinical and radiological follow-up, the Bryan CTDR has demonstrated a sustained clinical improvement and implant mobility over time, despite a moderate progression of degenerative processes at the prosthetic and adjacent levels.

Zeng et al. (2018) performed a retrospective study to assess the long-term clinical and radiographic outcomes of cervical disc arthroplasty (CDA) with Prestige-LP Disc at a minimum of 6-year follow-up. A total of 61 patients who underwent single- or two-level CDA with Prestige-LP Disc were included. Clinical assessments included visual analogue scale (VAS) for neck and arm pain, Neck Disability Index (NDI), and Japanese Orthopedic Association (JOA) score. Radiological evaluations included range of motion (ROM) of the index and adjacent levels, segmental angle, cervical sagittal alignment, heterotopic ossification (HO) and adjacent segment degeneration (ASD). Significant and maintained improvement in VAS for neck and arm, NDI and JOA were observed after a mean follow-up of 82.3 months. The preoperative ROM of the index level was 9.7° , which was maintained at 2- and 4-year follow-up, but was decreased to 8.0° at final follow-up. Mobility was maintained in 80.5% of the implanted prostheses at final follow-up. ROM of the superior and inferior adjacent segments, cervical sagittal alignment and cervical angle were all maintained. The incidence of HO was 42.9% at final follow-up, but it did not influence the clinical outcome. Radiographic ASD were detected in 29.5% of the patients. However, the incidence of symptomatic ASD was only 6.6%. The authors concluded that cervical disc arthroplasty with Prestige-LP Disc demonstrated a maintained and satisfactory clinical outcome at a minimal of 6-year follow-up, with majority of the prostheses remained mobile. Cervical disc arthroplasty with Prestige-LP Disc can be considered as an effective surgical method in treating CDDD.

Radcliff et al. (2017) reported on the results of the continuation of a prospective, multicenter, randomized, US FDA IDE clinical trial comparing cervical total disc replacement (TDR) with the Mobi-C® Cervical Disc versus anterior cervical discectomy and fusion (ACDF) through 7 years follow-up. Inclusion criteria included a diagnosis of symptomatic cervical degenerative disc disease at one or two cervical levels. TDR patients were treated using a Mobi-C® artificial disc. ACDF with allograft and anterior plate was used as a control treatment. Outcome measures were collected preoperatively and postoperatively at 6 weeks, at 3, 6, 12, 18 months, annually through 60 months, and at 84 months. Measured outcomes included Overall success, Neck Disability Index (NDI), VAS neck and arm pain, segmental range of motion (ROM), patient satisfaction, SF-12 MCS/PCS, major complications, and subsequent surgery rate. The primary endpoint was an FDA composite definition of success comprising clinical improvement and an absence of major complications and secondary surgery events. A total of 599 patients were enrolled and treated, with 164 treated with one-level TDR, 225 treated with two-level TDR, 81 treated with one-level ACDF, and 105 treated with two-level ACDF. At seven years, the overall success rates of two level TDR and ACDF patients were 60.8% and 34.2%, respectively. The overall success rates of one level TDR and ACDF patients were 55.2% and 50%, respectively. Both the single and two level TDR and ACDF groups showed significant improvement from baseline NDI scores, VAS neck and arm pain scores, and SF-12 MCS/PCS scores. In the single level cohort, there was an increased percentage of TDR patients who reported themselves as "very satisfied. There was a lower rate of adjacent level secondary surgery in the single level TDR patients versus the ACDF patients. In the two level TDR group, the NDI success rate was significantly greater in the TDR group. There was significantly more improvement in NDI change score at 7 years in the TDR patients versus ACDF. The TDR group had a significantly higher rate of patients who were "very satisfied" with their treatment compared to the ACDF group. The rate of subsequent surgery at the index level was significantly lower in the TDR group compared to the ACDF group. The rate of adjacent level secondary surgery was significantly lower in the two level TDR patients compared to the ACDF patients. In both single and two level cohorts, the percentage of patients with worse NDI (2.5%-3.8% of two level surgeries and 1.2%-2.5% of single level surgeries) or worse neck pain was strikingly low in both groups but trended lower in the TDR patients. The authors concluded that at seven years, the composite success analysis demonstrated clinical superiority of two level TDR over ACDF and non-inferiority of single level TDR versus ACDF. There were lower rates of secondary surgery and higher adjacent level disc survivorship in both groups. Both surgeries were remarkably effective in alleviating pain relative to baseline and the rate of patients with worse disability or neck pain was surprisingly low. Overall, greater than 95% of patients (from both groups) who underwent TDR and 88% of patients who underwent ACDF were "very satisfied" at seven years. The differences in clinical effectiveness of TDR versus ACDF becomes more apparent as treatment increases from one to two levels, indicating a significant benefit for TDR over ACDF for two-level procedures.

Lu and Peng (2017) conducted a systematic review and meta-analysis to compare the efficacy and safety of Mobi-C cervical artificial disc and anterior cervical discectomy and fusion (ACDF) in patients with symptomatic degenerative disc disease. Four randomized controlled trials (RCTs) assessing the effect of Mobi-C versus ACDF on the treatment of symptomatic degenerative disc disease were included. The primary outcomes were neck disability index (NDI) score, patient satisfaction, and subsequent surgical intervention. Meta-analysis was performed using the random-effect model. When compared with ACDF surgery in symptomatic degenerative disc disease, TDR using Mobi-C cervical artificial disc resulted in a significantly improved NDI score, patient satisfaction, and reduced subsequent surgical intervention. There was no significant difference of neurological deterioration, radiographic success, and overall success between TDR using Mobi-C cervical artificial disc versus ACDF surgery. The authors concluded that TDR using Mobi-C cervical artificial disc should be recommended for the treatment of symptomatic degenerative disc disease.

Chen et al. (2017) performed a systematic review and meta-analysis to assess the durability of cervical disc arthroplasties (CDAs) in at least 2-year follow-up. The classifications and causes of secondary surgical procedures, as well as the structural designs of the devices that might influence the durability were analyzed. The primary outcome was the rate of secondary surgical procedures following CDA or anterior cervical decompression and fusion (ACDF). Twelve randomized control trials (RCTs) met the inclusion criteria and included 2954 patients. Nine of twelve studies compared single-level CDA with ACDF and 3 studies investigated 2-level CDA. Follow-up ranged from 2 years to 7 years. A total of 103 secondary surgical procedures were performed. The most frequent classification of secondary surgical procedures was reoperation and removal. Adjacent-level diseases were the most common cause of reoperations. The rates of secondary surgical procedures were significantly lower in Mobi-C, Prestige, Prodisc-C, Secure-C group than in ACDF group. The authors concluded that Mobi-C, Secure-C, and Prodisc-C were more durable than ACDF. Precise selection of device size and proper surgical techniques are crucial to enhance the perdurability.

An August 2017 Hayes Medical Technology Comparative Effectiveness Review evaluated eleven (10 fair quality, 1 poor quality) randomized controlled trials (RCTs) that examined the effectiveness and safety of single-level artificial cervical total disc

replacement (TDR) compared with an anterior cervical discectomy and fusion (ACDF). Severity of neck disability appeared to be similar between treatments, or may even be lower among TDR patients. Arm and neck pain was either less severe with TDR, or similar between treatments. Neurological status outcomes appeared to be firmly similar with either treatment. Health-related quality of life (HRQOL) outcomes also appeared to be similar between the groups, although there is some evidence of better outcomes with TDR. Rates of adverse events appear to be similar between treatments. Rates of adjacent segment disease appear to be either similar, or lower, among TDR patients. The review found that in adult patients with cervical degenerative disc disease, there is generally consistent evidence that single-level TDR is either comparable with or superior to ACDF for both clinical efficacy and safety outcomes. Uncertainty remains related to outcomes beyond 7 years following surgery. (Report updated in August 2018 with no change to findings)

Hu et al. (2016) conducted a systematic review and meta-analysis to investigate the mid- to long-term outcomes of cervical disc arthroplasty (CDA) versus anterior cervical discectomy and fusion (ACDF) for the treatment of 1-level or 2-level symptomatic cervical disc disease. Eight prospective randomized controlled trials (RCTs) were included with 1317 and 1051 patients in CDA and ACDF groups, respectively. Overall success was considered achieved if a patient met all of the following items: NDI success, neurological success, absences of implant/surgery-related serious adverse events and secondary procedure. Pooled analysis showed patients in CDA group achieved significantly higher rates of overall success, Neck Disability Index (NDI) success, neurological success and significantly lower rates of implant/surgery-related serious adverse events and secondary procedure compared with that in ACDF group. The long-term functional outcomes (NDI, Visual Analog Scale (VAS) neck and arm pain scores, the Short Form 36 Health Survey physical component score (SF-36 PCS)), patient satisfaction and recommendation, and the incidence of superior adjacent segment degeneration also favored patients in CDA group with statistical difference. Patients in CDA group had a lower rate of inferior adjacent segment degeneration without statistical significance. The authors concluded that this meta-analysis showed that cervical disc arthroplasty was superior over anterior discectomy and fusion for the treatment of symptomatic cervical disc disease.

A meta-analysis was performed by Wu et al. (2016) which included randomized controlled trials that reported a minimum of 4 years of follow-up with regard to the rates of subsequent surgeries after artificial cervical disc replacement (ACDR) compared with anterior cervical discectomy and fusion (ACDF). The overall rate of subsequent surgery at the operated level and adjacent levels was lower in the ACDR group (7.4%) than in the ACDF group (16.8%). For subsequent surgery at the operated level or adjacent level, patients who received ACDR had a lower rate of subsequent surgery than patients who received ACDF. The authors concluded that ACDR had significantly fewer subsequent surgical interventions compared with ACDF, however, a review of the literature showed that there were an insufficient number of studies with respect to subsequent surgery with a minimum of 4 years of follow-up. Longer-term, multicenter studies are needed for better evaluation of the rate of subsequent surgery after ACDR.

Yao et al. (2016) performed a meta-analysis to compare the efficacy and safety of total disc arthroplasty (TDA) and anterior cervical discectomy and fusion (ACDF). Clinical indices included Neck Disability Index (NDI), Neurological Success (NS), Overall Success (OS), Return-to-Work Status (RWS), Reoperation (RO) and Implant/Surgical Procedure-Related Adverse Events (ISPRAE). A total of nine articles reporting on six trials with 2121 patients were included, in which 1082 underwent TDA and 1039 underwent ACDF. NDI scores were reported in five studies and did not differ significantly between the two groups. Neurological success was documented in 5 studies and the TDA group had significantly better neurological success compared with the ACDF group. Five studies provided data on overall success. The TDA group had significantly better overall success compared with the ACDF group. Return-to-work status after operation was reported in 3 studies and there was no significant difference between the two groups. Six trials reported data on secondary surgical procedures. The results showed that TDA is associated with significantly lower incidence of secondary surgical procedures than ACDF. Six trials reported on secondary surgical procedures at the adjacent level. There was no significant difference between the two groups. The authors summarized that based on the current literature review and meta-analysis; the clinical outcomes of TDA are equivalent or superior to ACDF. In addition, more long-term RCTs will be needed to corroborate the current conclusions.

The PRESTIGE® ST Cervical Disc consists of a two-piece articulating metal-on-metal device that is inserted into the intervertebral disc space at a single cervical level using an anterior approach. As part of approval, the FDA is requiring a seven-year post-approval study to evaluate long-term safety and effectiveness of the Prestige® ST Cervical Disc. Gornet et al. (2016) conducted a study to assess the safety and efficacy of the Prestige® LP Disc at 84-months follow-up. Prospective data from 280 cervical disc arthroplasty (CDA) patients with single-level cervical disc disease with radiculopathy or myelopathy were compared with 265 historical control anterior cervical discectomy and fusion (ACDF) patients. Clinical and radiographic follow up was completed pre-operatively, intraoperatively, and at intervals up to 84 months. Statistical improvements in Neck Disability

Index (NDI), neck/arm pain, and SF-36 were achieved by 1.5 months in both groups and maintained through 84 months. At 84 months, 86.1% of CDA versus 80.1% of ACDF patients achieved NDI success, (≥ 15 -point improvement over baseline). Mean NDI score improvements exceeded 30 points in both groups. SF-36 PCS/MCS mean improvements were $13.1 \pm 11.9/8.2 \pm 12.3$ points for CDA and $10.7 \pm 11.8/8.3 \pm 13.6$ points for ACDF. Neurological success was 92.8% for CDA and 79.7% for ACDF patients. The rate of Overall Success was 74.9% for CDA and 63.2% for ACDF. At 84 months, 17.5% of CDA and 16.6% of ACDF patients had a possibly implant- or implant-surgical procedure-related adverse event. Eighteen (6.4%) CDA and 29 (10.9%) ACDF patients had a second surgery at the index level. At 84 months, 90.9% of CDA and 85.6% of ACDF patients were satisfied with the results of their treatment. The authors concluded that Prestige LP maintained significantly improved clinical outcomes and segmental motion; statistical superiority of CDA was concluded for overall success. Additional studies are needed to establish long term efficacy.

A meta-analysis of randomized controlled trials (RCTs) was performed by Xie et al. (2016) to evaluate the efficacy and safety in cervical disc arthroplasty (CDA) and anterior cervical discectomy and fusion (ACDF) for treating cervical degenerative disc diseases (CDDDs). Twenty RCTs with a total 4004 patients (2212 in the CDA and 1792 in the ACDF) met inclusion criteria. Fifteen of the included studies were multi-center trials; five were single-center trials. Eight types of disc prostheses were used and patients were followed up for at least 2 years. The outcome measurements included neck disability index (NDI), neurological success, range of motion (ROM), Visual Analogue Score (VAS), adverse events, adjacent segment disease (ASD), and reoperation. The NDI score, VAS of neck and VAS of arm of the CDA group was significantly lower than that of the ACDF group. The rate of neurological success and ROM were significantly higher than that of the ACDF group. The authors concluded that the results of this meta-analysis indicated that CDA was superior to ACDF regarding fewer severe adverse events, fewer ASDs, fewer reoperations, better neurological success, greater ROM, lower NDI scores and greater neck and arm pain functional recovery. They recommended additional large, definitive RCTs.

Dejaegher et al. (2016) presented the 10-year follow-up results after implantation of the Bryan® Cervical Disc Prosthesis in a single center. Eighty-nine patients underwent implantation of a single-level Bryan® Cervical Disc Prosthesis to treat radiculopathy and/or myelopathy. Clinical outcomes measured include Neurological Success, Neck Disability Index (NDI), Neck- and Arm-Pain, and Short Form-36 (SF-36). Adverse events and second surgeries were recorded and evaluated. Maintenance or improvement of the neurological state was seen in 89% of patients after 10-year follow-up. SF-36 Physical Component Summary (PCS) scores improved significantly at all follow-up points. Significant improvement for NDI, and Neck- and Arm-Pain scores was found. Mean angular motion of the prosthesis at 10-year follow-up was 8.6° . Mobility of the device, defined as $>2^\circ$ of angular motion, was reached in 81% of patients. During the study period, 21 patients (24%) developed new or recurrent radiculopathy or myelopathy, the majority of these being treated conservatively. Seven patients (8%) required 8 additional spine surgeries to treat persistent or recurrent symptoms. In this study, favorable long-term clinical outcome after implantation of the Bryan® Cervical Disc Prosthesis was seen, with the majority of prostheses remaining mobile after 10-year follow-up. However, still 6% of patients required adjacent level surgery.

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.”

In September 2012, ECRI Institute published an evidence based report evaluating cervical disc replacement that included evidence published until April 2012. Eleven publications met the inclusion criteria, six were randomized controlled trials and five consisted of case series. The evidence reviewed by ECRI did not permit conclusions regarding rate of occurrence of adverse events.

Huppert et al. (2011) conducted a prospective multicenter study to compare the clinical and radiological outcomes of cervical disc replacement between single- (n=175) and multilevel (n=56) patients receiving the Mobi-C® device. Follow-up (FU) evaluation was performed at 1, 3, 6, 12, and 24 months after surgery. Comparison between both groups was based on Neck Disability Index (NDI), Visual Analog Scale (VAS), and Range of Motion. At 24 months, mean NDI and VAS scores for neck and arm pain were improved in both groups similarly. Improvement in range of motion was also similar with the single level group having an

increase of 2.8 degrees compared to 2.2 degrees in the multilevel group. Post-operative analgesic use was higher in the multilevel group at 53% compared to 32% for the single level group. Complications occurred in 19 of the 175 (10.9%) single level patients compared to 11 in the 56 (19.6%) multilevel patients. The rate of dysphagia/dysphonia was significantly higher in the multi-level group (9/56 or 16%) versus (6/175 or 3.4%) in the single-level group. Four patients in the single level group underwent a secondary surgery (2 fusions; 2 disc replacement) versus 2 patients in the multilevel group that had a third device implanted. There were no significant differences between the groups however additional studies are needed to evaluate the impact on safety and efficacy for multilevel disc replacement.

Kelly et al. (2011) compared adjacent segment motion following disc arthroplasty using the ProDisc-C® device versus anterior cervical discectomy and fusion (ACDF) in 209 patients in a prospective randomized controlled trial at 13 sites. The authors reported no significant difference in adjacent segment range of motion (ROM) was observed between ACDF and TDA. Only time was a significant predictor of postoperative ROM at both the cranial and caudal adjacent segments. The ROM decreased over time with fusion whereas disc replacement results in immediate motion sustained throughout the follow-up period.

Delamarter et al. (2010) presented the preliminary 4 year follow-up results of the Murrey IDE study. The follow-up rates at 48 months for ProDisc-C® TDR and ACDF were 63.0% and 46.2%, respectively, at the time of publication. After closure of randomized enrollment an additional group of 136 continued access (CA) patients had ProDisc-C® TDR surgery. At 24 months, there was no significant difference in neurologic improvement among the 3 groups. At 48 months, the overall neurologic improvement trended toward significance for ProDisc-C® TDR patients compared with ACDF patients. VAS scores decreased at 24 months in all 3 groups. At 48 months the ACDF group showed only a 38.7 mm reduction in mean VAS score from preoperative levels compared with 49.3 mm in the ProDisc-C® TDR group, although this difference was not statistically significant. On radiographic exam at 24 months, flexion-extension range of motion (ROM) at the index level was similar between the Pro-Disc-C® TDR and the CA group (9.38° and 9.50°). ROM was <2° in 91.2% of the ACDF patients at 24 months. At 48 months, flexion-extension ROM was maintained in Pro-Disc-C® TDR group (9.12°), and 95.5% of the ACDF group had <2° ROM. Of the original study participants, (103 Pro-Disc® and 106 ACDF), 11 patients (2 Pro-Disc-C® and 9 ACDF) required secondary surgical procedures by 24 months. The 3 Pro-Disc® patients converted to fusion. In the ACDF group, 6 underwent additional fusion at both the index and adjacent levels, 1 had a revision due to dysphagia associated with plate liftoff, and 1 had posterior decompression with supplemental fixation. By 48 months, 3 of Pro-Disc-C® TDR patients and 12 of ACDF patients had required a secondary surgical procedure. The authors conclude that preliminary data at 4 years shows that both total disc replacement and ACDF are viable surgical options for patients with symptomatic cervical disk disease.

Heidecke et al. (2008) conducted a prospective study of 54 consecutive patients with degenerative cervical disease who underwent ventral discectomy and disc replacement with the Bryan® Cervical Disc prosthesis. A total of 59 prosthetic discs were implanted, in 49 patients at a single level and in 5 at two adjacent levels. Neurological status was evaluated pre-operatively and at one and two years thereafter. Plain X-rays, CT, and MRI were used for pre-operative diagnostics. Post-operative follow-up was done by X-rays. Clinical results and functional outcome at 2 years showed that all patients reported excellent or good neurological outcome. Seven patients experienced loss of mobility, mainly due to the development of heterotopic ossification. Further investigations with longer follow-up periods and with a control group (e.g. fusion with intervertebral cage) will be necessary for a definitive assessment of the long-term functionality and benefits of artificial cervical discs.

Goffin et al. (2010) reported on 4- and 6-year follow-up results after cervical disc replacement surgery using the Bryan® Cervical Disc Prosthesis. A total of 98 patients (89 with 1-level and 9 with 2-level implantations) participated in the follow-up studies for up to 10 years postoperatively. Outcomes were measured utilizing the 36-Item Short Form Health Survey, Neck Disability Index, numerical ratings of neck and arm pain, neurological outcomes, Odom classification and angular motion findings from lateral flexion-extension radiographs. The mean angular motion results at 4 and 6 years postoperatively for 1-level patients were 7.3 and 7.7°, respectively. Two-level patients had slightly less motion at 4 and 6 years postoperatively with mean caudad values of 5.7 and 6.0°, respectively, and cephalad values of 4.2 and 6.2°, respectively. A total of 65 patients (61 1-level and 4 2-level patients) had at least 1 adverse event recorded however only 6 of these were judged to be related to the device. These events included device migration, device removal, hoarseness and vocal cord paralysis, as well as 3 cases involving pain and neurological symptoms. In addition, 8 patients underwent further neck surgery to treat symptoms. The authors conclude that favorable outcomes persist after 4-6 years of follow-up. The study was manufacturer sponsored and is limited by small sample size and subjective outcomes.

A study by Walraevens et al. (2010) of the same 89 patients in the Goffin study above assessed the intermediate and long-term radiographic characteristics of disk replacement surgery with the Bryan® Cervical Disc. There were no cases of anteroposterior

migration or subsidence. Mobility at the treated level was preserved in $\geq 85\%$ of cases. The authors concluded that the device maintains preoperative motion at the index and adjacent levels, seems to protect against acceleration of adjacent-level degeneration as seen after anterior cervical discectomy and fusion, and remains securely anchored in the adjacent bone mass in the long run.

In 2010, the National Institute for Health and Care Excellence (NICE) issued a guidance statement on the use of prosthetic intervertebral disc replacement in the cervical spine. NICE concluded that the current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is at least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. They further state that the evidence raises no particular safety issues that are not already known in relation to fusion procedures.

Professional Societies

American Academy of Orthopaedic Surgeons (AAOS)

Although it is not an official position statement, in 2010 the AAOS published a technology overview of cervical disc arthroplasty. The committee addressed four key questions regarding the technology, comparing the outcomes of patients treated with cervical intervertebral disc (IVD) replacement to patients treated with anterior cervical disc fusion (ACDF). The key questions addressed what patient characteristics predicted successful outcomes in patients who underwent cervical IVD replacement compared to ACDF; do patients with herniated disc and arm pain, with or without neck pain, have equal or better outcomes when compared to ACDF, are the revision rates and/or complication rates equal or better in those who receive disc replacement compared to ACDF, and for patients which is more economical, according to hospital length of stay and return to work. Regarding patient characteristics, the data was inconclusive, most studies did not report a statistical analysis, and only one level II study reported no statistically significant difference. For clinical outcomes, five level II studies were included. There was a trend for better NDI scores and NDI success rate at early follow-up, data for long term follow-up was inconclusive. While one study reported arthroplasty had significantly higher neurologic success rates, two level II studies reported no statistically significant differences. A majority of the studies reported no statistically significant difference in either neck or arm pain scores at short term follow-up (six months to 24 months), long term data was inconclusive. The result reported by three level II studies was inconclusive regarding SF-36 scores and there were no differences in the number of patients who returned to work at 24 months. The results of four level II studies were included, three did not report secondary surgery results similarly, and therefore the results could not be compared. The results for adverse events were also inconclusive in these same studies. Patients who underwent arthroplasty returned to work in significantly fewer days although the length of hospital stay did not vary between groups.

International Society for the Advancement of Spine Surgery (ISASS)

The ISASS published a policy statement (ISASS, 2014) supporting the safety and efficacy of cervical disc arthroplasty as an alternative to anterior cervical discectomy and fusion for individuals with one or two level cervical radiculopathy or myelopathy.

North American Spine Society (NASS)

The 2015 Cervical Artificial Disc Replacement (CADR) Coverage Policy Recommendation states that CADR may be indicated for the following diagnoses with qualifying criteria, when appropriate:

- Radiculopathy related to nerve root compression from one or 2-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain that has been refractory to medical or nonoperative management.
- Myelopathy or myeloradiculopathy related to central spinal stenosis from one or 2 level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain.

There is not significant evidence to support its use for 3 or more levels or in the case of adjacent segment disease following an index fusion.

Cervical Artificial Disc (Two Level)

A 2019 Ontario health technology assessment (Pron et al., 2019) examined the effectiveness, safety, durability, and cost-effectiveness of cervical artificial disc replacement (C-ADR) versus fusion for treating cervical degenerative disc disease. A systematic literature search of the clinical evidence comparing C-ADR with fusion was performed. Eight studies of C-ADR for one-level cervical degenerative disc disease and two studies of C-ADR for two-level disease were included. In two studies of C-

ADR for two-level disease, C-ADR was statistically superior to fusion surgery for the same primary outcome. C-ADR was also noninferior to fusion for perioperative outcomes (e.g., operative time, blood loss), patient satisfaction, and health-related quality of life. C-ADR was superior to fusion for recovery and return to work, had higher technical success, and had lower rates of reoperation at the index site. C-ADR also maintained motion at the index-treated cervical level, but evidence was insufficient to determine if adjacent-level surgery rates differed between C-ADR and fusion. Current evidence was insufficient to determine the long-term durability of C-ADR. The authors concluded that for carefully selected patients with cervical degenerative disc disease, C-ADR provides patient-important and statistically significant reductions in pain and disability. Unlike fusion, C-ADR allows people to maintain relatively normal cervical spine motion.

A study was performed by Gao et al. (2019) to present a long-term clinical and radiographic comparison between the Prestige LP cervical disc replacement and the Zero-P spacer cervical disc fusion in the treatment of patients with symptomatic 2-level cervical degenerative disease. In total, 36 patients in the anterior cervical discectomy and fusion (ACDF) group and 24 patients in the cervical disc arthroplasty (CDA) group were analyzed before surgery and at 1 week and 3, 6, 12, 24, and 60 months after surgery. Mean follow-up period was 65.6 months. Both the ACDF and CDA groups showed significant clinical improvements in terms of Japanese Orthopaedic Association score, visual analog scale, and Neck Disability Index, but there was no significant difference between groups at the last follow-up period. A significant increase of cervical lordosis was observed in the CDA group after surgery whereas a significant difference was not observed between groups. Range of motion (ROM) of the total cervical spine and functional spinal unit (FSU) were maintained during the follow-up, and a significant decrease was observed in the ACDF group after surgery. The ROM of the superior adjacent segment did not show any difference whereas the ROM of the inferior adjacent segment in the ACDF group presented a significant increase at 6 months and 1 year after surgery and a significant decrease at the last follow-up period. A total of 8 (33.3%) patients in the CDA group had an occurrence of heterotopic ossification. Adjacent-segment degeneration (ASD) was observed in 2 (8.3%) patients who underwent CDA surgery and 8 (22.2%) patients who underwent ACDF surgery. The authors concluded that the use of the Prestige-LP and ZERO-P Spacer implantations is safe and effective. At 5 years after surgery, CDA with Prestige-LP is superior in terms of ROM of the total cervical spine, FSU, and inferior adjacent segment. It also has a relatively low occurrence rate of ASD.

Zhao et al. (2018) conducted a systematic review and meta-analysis to compare the efficacy and safety of anterior cervical artificial disc replacement (ACDR) and anterior cervical decompression and fusion (ACDF) in patients with 2 contiguous levels cervical spondylosis. The following outcome measures were extracted: neck disability index (NDI), visual analog scale (VAS) neck, VAS arm, Short Form (SF)-12 mental component summary (MCS), SF-12 physical component summary (PCS), overall clinical success (OCS), patient satisfaction (PS), device-related adverse event (DRAE), subsequent surgical intervention (SSI), neurological deterioration (ND), and adjacent segment degeneration (ASD). Nine randomized controlled trials and 2 clinical controlled trial studies containing 2715 patients were included for this meta-analysis. The pooled analysis indicated that the ACDR group is superior to ACDF in NDI, VAS neck, PCS score, OCS, PS, DRAE, ASD, and SSI. There was no significant difference in the ND, VAS arm and in MCS score. The authors concluded that the meta-analysis suggests that for bi-level cervical spondylosis, ACDR appears to provide superior clinical effectiveness and safety effects than ACDF. More well designed studies with large samples are needed to provide further evidence for the effect and reliability of ACDR compared with ACDF in the treatment of cervical spondylosis.

Yang et al. (2018) performed a study to evaluate the superiority of total disc replacement (TDR) using a cervical disk prosthesis vs anterior cervical discectomy and fusion (ACDF). Ninety-six patients with a diagnosis of degenerative disk disease with radiculopathy or myeloradiculopathy at 2 contiguous levels from C-3 to C-7 were randomly allocated to the TDR group (n=48) or the ACDF group (n=48). Outcome measures were recorded preoperatively and 1 week and 3, 6, 12, 24, and 81 months postoperatively. A total of 80 patients completed the follow-up, including 38 in the TDR group and 42 in the ACDF group. Japanese Orthopaedic Association, visual analog scale, and Neck Disability Index scores showed statistically significant improvement from baseline in both groups. The ACDF group had statistically greater visual analog scale scores from 12 months and Neck Disability Index scores from 3 months. The TDR group had statistically greater range of motion at both the superior and the inferior treated levels at 3, 6, 12, 24, and 81 months postoperatively. The ACDF group had statistically greater range of motion at the superior adjacent levels at 6, 12, 24, and 81 months and at the inferior adjacent levels at 24 and 81 months postoperatively. The occurrence of adjacent-segment degeneration at both the superior and the inferior adjacent levels was greater in the ACDF group than in the TDR group. The authors concluded that total disc replacement was safe and effective and a statistically superior alternative to ACDF for degenerative disk disease at 2 contiguous levels.

A systematic review was performed (Chang et al. 2017) to evaluate the difference in rate of reoperation for adjacent segment disease (ASD) between anterior cervical decompression and fusion (ACDF) and total disc replacement (TDR). Nine studies met

the inclusion criteria with a length of follow-up between 24 and 80 months. The total number of patients treated with TDR was 1,864 and 1,572 treated with ACDF. The average reoperation rate for ASD was 3.1% for the TDR cohort and 6.0% in the ACDF group. The authors concluded that further studies and follow-up data are needed to determine if cervical TDR preserves adjacent segment motion more efficiently than the natural history of the disease.

A systematic review was conducted by Joaquim et al. (2017) of clinical studies evaluating patients who underwent multilevel cervical disc arthroplasty (CDA) (2 or more levels). Fourteen studies met inclusion criteria and included: 1) studies comparing multilevel CDA versus anterior cervical discectomy and fusion (ACDF); 2) studies comparing single-level CDA versus multilevel CDA; and 3) multilevel CDA after a previous cervical spine surgery. The authors reported that multilevel CDA was at least as safe and effective as ACDF, with preservation of cervical motion when compared with ACDF and with fewer reoperations. Multilevel CDAs are clinically effective as single-level surgeries, with good clinical and radiological outcomes. Some studies reported a higher incidence of heterotopic ossification in multilevel CDA when compared with single-level procedures, but without clinical relevance during the follow-up period. The authors concluded that the current literature supports the use of multilevel CDA but caution is necessary regarding the more restrictive indications for CDA when compared with ACDF.

Gornet et al. (2017) conducted a prospective, multicenter randomized control trial to compare the efficacy and safety of arthroplasty using the Prestige LP cervical disc with those of anterior cervical discectomy and fusion (ACDF) for the treatment of degenerative disc disease (DDD) at 2 adjacent levels. Individuals were randomized to 1 of 2 groups: investigational patients (209) underwent arthroplasty using a Prestige LP artificial disc, and control patients (188) underwent ACDF and were followed up to 24 months. Treatment was considered an overall success when all 4 of the following criteria were met: 1) NDI score improvement of ≥ 15 points over the preoperative score, 2) maintenance or improvement in neurological status compared with preoperatively, 3) no serious AE caused by the implant or by the implant and surgical procedure, and 4) no additional surgery (supplemental fixation, revision, or nonelective implant removal). The overall success rate was 81.4% for the investigational group and 69.4% for the control group. There was no statistical difference between the groups in terms of adverse events (AE) but the ACDF group had a higher rate of Grade 3 or 4 AEs. Heterotopic ossification was identified in 27.8% of the superior levels and 36.4% of the inferior levels of the investigational patients at 24 months. The authors concluded that arthroplasty with the Prestige LP cervical disc is as effective and safe as ACDF for the treatment of cervical DDD at 2 contiguous levels and is an alternative treatment for intractable radiculopathy or myelopathy at 2 adjacent levels.

Lanman et al. (2017) reported on the prospective, randomized, controlled, multicenter FDA-approved clinical trial which assessed the long-term clinical safety and effectiveness in patients (n=209) undergoing anterior cervical surgery using the Prestige LP artificial disc replacement (ADR) prosthesis to treat degenerative cervical spine disease at 2 adjacent levels compared with anterior cervical discectomy and fusion (ACDF) (n=188). There was no statistically significant difference in the overall rate of implant-related or implant/surgical procedure-related adverse events. The Prestige LP group had fewer serious (Grade 3 or 4) implant or implant/surgical procedure-related adverse events. Patients in the Prestige LP group also underwent fewer second surgical procedures at the index levels (4.2%) than the fusion group (14.7%). Angular range of motion at superior- and inferior-treated levels was maintained in the Prestige LP ADR group to 84 months. The authors concluded that at 84 months, the Prestige LP ADR demonstrated statistical superiority over fusion for overall success and implanted at 2 adjacent levels, maintains improved clinical outcomes and segmental motion and is a safe and effective alternative to fusion.

A 2017 Hayes Medical Technology Comparative Effectiveness Review included eight studies that examined the effectiveness and safety of 2-level artificial cervical total disc replacement (TDR) compared with anterior cervical discectomy and fusion (ACDF). The overall quality of the evidence was rated as low. The review found that two-level TDR is at least as effective as ACDF and sometimes more effective for improving symptoms of patients with cervical degenerative disc disease (DDD), with clinically meaningful effects lasting as long as 7 years. TDR poses no obvious safety concerns compared with ACDF. It concluded that there is a need for additional, well-designed RCTs to further evaluate the long-term safety and effectiveness of 2-level and multilevel cervical TDR. (Updated October 2018 with no change in recommendation)

The purpose of a study by Radcliff et al. (2016) was to report the outcome of a study of 2-level cervical total disc replacement (Mobi-C[®]) versus anterior cervical discectomy and fusion (ACDF). This study reports the 5-year results of a prospective, randomized US FDA investigational device exemption (IDE) study conducted at 24 centers in patients with 2-level, contiguous, cervical spondylosis. Clinical outcomes at up to 60 months were evaluated, including validated outcome measures, incidence of reoperation, and adverse events. A total of 225 patients received the Mobi-C[®] cervical total disc replacement device and 105 patients received ACDF. The Mobi-C[®] and ACDF follow-up rates were 90.7% and 86.7%, respectively, at 60 months. There was significant improvement in all outcome scores relative to baseline at all time points. The Mobi-C[®] patients had significantly more

improvement than ACDF patients in terms of Neck Disability Index score, SF-12 Physical Component Summary, and overall satisfaction with treatment at 60 months. The reoperation rate was significantly lower with Mobi-C® (4%) versus ACDF (16%). There were no significant differences in the adverse event rate between groups. The authors concluded that there was significantly greater improvement in general in disease-specific outcome measures and a lower rate of reoperation in the 2-level disc replacement patients versus ACDF control patients.

Zou et al. (2016) conducted a meta-analysis of randomized controlled trials to evaluate the clinical effects requiring surgical intervention between anterior cervical discectomy and fusion (ACDF) and cervical disc arthroplasty (CDA) at two contiguous levels cervical disc degeneration. The overall sample size at baseline was 650 patients (317 in the TDR group and 333 in the ACDF group). The results of the meta-analysis indicated that the CDA patients had significant superiorities in mean blood loss, reoperation, adjacent segment degeneration and Neck Disability Index. No significant difference was identified between the two groups regarding mean surgical time, neck and arm pain scores reported on a visual analog scale and rate of postoperative complications. The CDA group of sagittal range of motion (ROM) of the operated and adjacent levels, functional segment units (FSU) and C2-7 is superior to ACDF group by radiographic data of preoperation, postoperation and follow-up. The authors concluded that the cervical disc arthroplasty (CDA) group is equivalent and in some aspects has more significant clinical outcomes than the ACDF group at two contiguous levels cervical disc degeneration.

Hybrid Surgery

Artificial disc replacement at one level combined with spinal fusion surgery at another level (adjacent or non-adjacent) is referred to as hybrid surgery. There are few clinical trials to support improved health outcomes and patient selection criteria has not been firmly established.

Through a systematic review of both published and ongoing studies on single- and multilevel cervical disc arthroplasty (CDA) and hybrid surgeries, Laratta et al. (2018) aimed to provide evidence for their safety and efficacy in the treatment of various cervical pathologies. Among the relevant studies reviewed, 3 were randomized controlled trials, 2 systematic reviews, as well as multiple prospective case series, biomechanical studies, and meta-analyses. The authors concluded that multiple studies show that single-level CDA can offer equivalent clinical outcomes with a reduction in secondary procedures and total cost when compared to ACDF. Recently there has been an increasing prevalence of 2-level CDA and hybrid surgery (HS). The data regarding these multilevel procedures is less robust. More high quality evidence with large patient populations is necessary to accurately and critically assess the utility of multilevel CDA and HS.

A systematic review and meta-analysis was conducted by Lu et al. (2017) to compare the outcomes of hybrid surgery (HS) versus anterior cervical discectomy and fusion (ACDF) for the treatment of multi-level cervical disc disease (mCDD). Eight studies were identified, 169 patients undergoing HS were compared with 193 ACDF procedures. HS was associated with greater C2-C7 range of motion (ROM) preservation and less functional impairment after surgery compared to ACDF. There was no significant difference between HS and ACDF with respect to postoperative pain, postoperative complication rates and length of stay. The authors concluded that HS is a novel surgical approach to treat mCDD, associated with a greater operative time, less intraoperative blood loss and comparable if not superior clinical outcomes compared to ACDF. There is a lack of robust clinical evidence in the literature. Further research with randomized controlled trials is needed to validate these findings.

Chen et al. (2016) retrospectively analyzed data from 108 patients with three-level cervical myelopathy who underwent hybrid surgery. Implantation of Bryan® artificial discs into two contiguous segments and cage fusion of adjacent segments was performed for all patients. Based on the Japanese Orthopedic Association (JOA) score, Neck Disability Index (NDI), and Odom's criteria, the clinical symptoms and neurological function before and after surgery were evaluated. Mean follow-up duration was 36 months. At the final follow-up, the mean JOA scores were higher compared with preoperative values (15.08 ± 1.47 versus 9.18 ± 1.22) and the NDI values were decreased (12.32 ± 1.03 versus 42.68 ± 1.83). The clinical outcomes were rated as excellent (76 patients), good (22 patients), fair (six patients), and poor (four patients) based on Odom's criteria. For patients with predominant nerve root symptoms, radicular pain of the upper limbs showed remission; in those with dominant symptoms of spinal cord compression, both muscle strength and sensation improved. Mean range of motion of segments with replaced artificial discs was not significantly different from the value obtained before surgery; the overall ROM of the cervical vertebrae was similar to the pre-surgery value. The main complications include postoperative infection, prosthesis movement, dysphagia, dysphonia, and heterotopic ossification. The authors concluded that these findings suggested a satisfactory clinical effectiveness for hybrid surgery but additional multicenter, long-term follow-up studies with large populations are needed to validate these findings.

Shi and colleagues (2015) performed a retrospective review of 36 patients with adjacent three-level cervical spondylosis who were treated with anterior cervical discectomy and fusion (ACDF) combined with cervical disc arthroplasty (CDA) (hybrid surgery) between October 2008 and October 2012. Clinical evaluation was based on the Neck Disability Index (NDI), Japanese Orthopaedic Association (JOA) score, and postoperative JOA score improvement rate (IR). Radiographic parameters, angular range of motion (ROM) for C2-C7, and ROM for the superior and inferior adjacent segments were measured before the operation, at 1, 3, 6, and 12 months post operation, and at the final follow-up evaluation. All cases were followed for at least 28 months. There was a significant postoperative improvement in NDI and JOA scores compared to preoperative levels. The JOA score improvement rate was 70.83 % at the final follow-up evaluation. One patient required a second surgery for symptomatic adjacent segment degeneration. The mean C2-C7 ROM, which was $46.39 \pm 2.41^\circ$ before the operation, was recovered after 12 months ($46.03 \pm 4.64^\circ$) and was maintained at the last follow-up evaluation ($47.50 \pm 4.59^\circ$). The ROM of the superior and inferior adjacent segments, which was $14.25 \pm 1.81^\circ$ and $10.89 \pm 1.65^\circ$ before the operation, respectively, was recovered after 6 months ($14.03 \pm 1.46^\circ$ and $10.75 \pm 2.37^\circ$, respectively) and increased at the last follow-up evaluation ($15.00 \pm 1.15^\circ$ and $11.47 \pm 1.84^\circ$, respectively). During the follow-up period, heterotopic ossification occurred in three patients. Adjacent segment degeneration was encountered in two cases, and one of these required a second surgical treatment. The authors concluded that the results indicate that hybrid surgery seems to be a promising, acceptable, and alternative surgical approach for the treatment of multi-level cervical disc disease. Some authors have investigated this method of treatment but the evidence in the published peer-reviewed literature is limited by lack of controls, small sample size and short term outcomes. Additional research is needed to clearly establish a role for hybrid technologies.

Lumbar Artificial Disc

Li et al. (2018) conducted an updated systematic review and meta-analysis to compare the efficacy and safety of total disc replacement (TDR) versus lumbar fusion. A total of 7 randomized controlled trials (RCTs) (1706 patients) were included. Patients in TDR group had significant improvements in ODI, VAS scores, complication rates and had a greater percentage of being satisfied with the surgery. In addition, the clinical success in TDR group was higher than fusion group. TDR treated patients had shorter operating time and shorter duration of hospital stay. There was no clinical significance between two groups at blood loss, work status and reoperation rate. The authors concluded that the meta-analysis showed that TDR proved superiorities in improved clinical success, reduced pain, patients' satisfaction, shortened hospital stay and operating time and lessened complication rate. But there were no benefits in blood loss.

Mu et al. (2018) conducted a systematic review and meta-analysis to compare the efficacy and safety of lumbar total disc replacement (TDR) with the efficacy and safety of anterior lumbar interbody fusion (ALIF) for the treatment of lumbar degenerative disc disease (LDDD). Six studies (5 randomized controlled trials (RCT) and 1 observational study) involving 1093 patients were included. Operative time, intraoperative blood loss, hospital stay, complications and re-operation rate were without significant clinical difference between groups. Patients in the TDR group had higher postoperative satisfaction and, better improvements in ODI, VAS and postoperative lumbar mobility than did patients in the ALIF group. The authors concluded that TDR had significant reduction in clinical symptoms, improved physical function and preserved range of motion for the treatment of LDDD compared to ALIF. TDR may be an ideal alternative for the selected patients with LDDD in the short-term. More studies that are well-designed, that are of high-quality and that have larger samples are needed to further evaluate the efficacy and safety of TDR at the long-term follow-up.

Zigler et al. (2018b) conducted a meta-analysis to evaluate the long-term efficacy and safety of total disc replacement (TDR) compared with fusion in patients with functionally disabling chronic low back pain due to single-level lumbar degenerative disc disease (DDD) at 5 years. PubMed and Cochrane Central Register of Controlled Trials databases were searched for randomized controlled trials reporting outcomes at 5 years for TDR compared with fusion in patients with single-level lumbar DDD. Outcomes included Oswestry Disability Index (ODI) success, back pain scores, reoperations, and patient satisfaction. The meta-analysis included 4 studies. TDR patients had a significantly greater likelihood of ODI success and patient satisfaction and a significantly lower risk of reoperation than fusion patients. Long-term improvement in back pain scores were similar between TDR and fusion. Results for ODI success and patient satisfaction were sensitive to different outcome definitions but remained in favor of TDR. The authors concluded that TDR is an effective alternative to fusion for lumbar DDD.

Zigler et al. (2018a) conducted a network meta-analysis to compare the efficacy and safety of total disc replacement, lumbar fusion, and conservative care in the treatment of single-level lumbar degenerative disc disease (DDD). Outcomes measured at 2 year follow-up included Oswestry Disability Index (ODI) success, back pain score, patient satisfaction, employment status, and reoperation. Randomized controlled trials that included patients with discogenic low back pain due to single-level lumbar DDD, who were unresponsive to conservative therapy, were considered if they compared a TDR device (Charite, ProDisc-L, Maverick,

Kineflex-L, Flexicore, activL) with other total disc replacement devices, fusion (anterior, posterior, or circumferential) or conservative care (rehabilitation, exercise). Six studies were included (1417 participants). Evidence from several studies shows that arthroplasty is superior to fusion and conservative care. The authors concluded that overall, the activL total disc replacement device had the most favorable results for ODI success, back pain, and patient satisfaction. Results for employment status and reoperation were similar across therapies.

A systematic review was conducted by Cui et al. (2018) to evaluate the mid- to long-term clinical outcomes of artificial total disc replacement (TDR) for lumbar degenerative disc diseases. Thirteen studies, including eight prospective studies and five retrospective studies, were included. A total of 946 patients were identified who reported at least 3 years of follow-up results. A total of 1048 prostheses were implanted, single-segment TDRs were performed on 872 patients, and multi-segment TDRs were performed on 88 patients. A total of 369 prostheses were implanted into level L4/L5, 543 prostheses were implanted into level L5/S1, and 51 were implanted into other segments. Patients with lumbar TDR demonstrated significant improvements in VAS scores of 51.1 to 70.5% and of -15.6 to -44.4 for Oswestry disability index (ODI) scores at the last follow-up. Patient satisfaction rates were reported in eight studies and ranged from 75.5 to 93.3%. Complication rates were reported in 11 studies, ranging from 0 to 34.4%. The overall reoperation rate was 12.1% (119/986), ranging from 0 to 39.3%, with eight of the 13 studies reporting a reoperation rate of less than 10%. The authors concluded that the study shows that lumbar TDR effectively resulted in pain relief and an improvement in quality of life at mid- to long-term follow-up. Complication and reoperation rates were acceptable. This study did not provide sufficient evidence to show that lumbar TDR is superior to fusion surgery. A greater number of high-quality randomized controlled trials (RCTs) are needed.

A 2018 ECRI Health Technology Assessment Product Brief for ActivL artificial disc identified evidence from 1 systematic review with a network meta-analysis of 6 randomized controlled trials (RCTs) indicating that the activL artificial disc reduced back pain and improved the ability to perform daily tasks more than Prodisc-L® or Charite total disc replacements (TDR); reoperation rates were similar. Evidence on the indirect comparisons with fusion and conservative treatment was too weak to permit conclusions. The report concludes that findings warrant confirmation in additional RCTs comparing activL with other TDR systems and RCTs comparing activL with lumbar fusion and reporting longer-term outcomes (>3 years), but none are ongoing (ECRI, 2018).

A prospective study was performed by Scott-Young et al. (2018) to evaluate clinical and patient outcomes post combined total disc arthroplasty (TDA) and anterior lumbar interbody fusion (ALIF), known as hybrid surgery for the treatment of multilevel symptomatic degenerative disc disease (DDD). A total of 617 patients underwent hybrid surgery for chronic back pain between July 1998 and February 2012. Visual Analog Pain Scale for the back and leg were recorded along with the Oswestry Disability Index and Roland Morris Disability Questionnaire. The authors report both statistically and clinically significant reductions were seen in back and leg pain, which were sustained for at least 8 years post surgery. Significant improvements were also seen in self-rated physical disability and function, also maintained for at least 8 years. Patient satisfaction was rated as good or excellent in >90% of cases. They concluded that the results of this study suggest TDA with ALIF is a suitable option for patients suffering chronic back and leg pain secondary to multilevel DDD when conservative management fails. A limitation to the present study is that not all patients experienced leg pain preoperatively and, therefore, their baseline score would be zero. The findings of this study need to be validated by well-designed studies.

Formica et al. (2017) performed a systematic review to summarize the available evidence about total lumbar disc replacement (TDR), focusing on clinical and functional outcomes, comparison with fusion surgery results, rate of complications and influence on sagittal balance. Fifty-nine studies were included. Clinical and functional scores showed statistically significant improvements to baseline. There was no significant difference between TDR groups and fusion groups. There were similar rates of complications between the two surgical procedures. TDR showed significant safety and efficacy, comparable to lumbar fusion. The authors summarized that the major advantages of a lumbar TDR over fusion included maintenance of segmental motion and the restoration of the disc height, allowing patients to find their own spinal balance. The authors concluded that disc arthroplasty could be a reliable option in the treatment of degenerative disc disease. They recommended further studies with larger groups of patients and a longer follow-up period to better evaluate the outcomes and safety of lumbar TDR.

A systematic review of overlapping meta-analyses comparing total disc replacement (TDR) with fusion for treating lumbar degenerative disc disease (LDDD) was conducted by Ding et al. (2017). Five meta-analyses only comprising randomized controlled trials (RCTs) were included. This systematic review showed that there are conflicting results among these overlapping meta-analyses. Based on this systematic review, the best available evidence indicated that TDR compared with fusion for LDDD had statistically, but not clinically, significant superiority regarding disability, pain relief, and quality of life in a selected group of patients in the short term. The prevention of adjacent segment and facet joint degeneration, as the primary

reason for adopting TDR noted by the manufactures, was not appropriately evaluated. This study could not assess the long-term results, because almost all of the primary studies only have data for 2 years. The authors concluded the current best available evidence suggests that TDR may be an effective technique for the treatment of selected patients with LDDD, and is at least equal to lumbar fusion in the short term. However, considering that disadvantages may appear after years, spine surgeons should be cautious about performing TDR on a large scale.

A multicenter randomized controlled trial was conducted by Furunes et al. (2017) to assess the long-term relative efficacy of lumbar total disc replacement (TDR) compared with multidisciplinary rehabilitation (MDR). One hundred seventy-three patients with chronic low back pain (LBP) and localized degenerative changes in the lumbar intervertebral discs were randomly assigned treatment. The primary outcome was self-reported physical function (Oswestry Disability Index [ODI]) at 8-year follow-up in the intention-to-treat population. Secondary outcomes included self-reported LBP (visual analogue scale [VAS]), quality of life (EuroQol [EQ-5D]), emotional distress (Hopkins Symptom Checklist [HSCL-25]), occupational status, patient satisfaction, drug use, complications, and additional back surgery. Seventy-seven patients (90%) who were randomized to surgery and 74 patients (85%) randomized to rehabilitation responded at 8-year follow-up. Mean improvement in the ODI was 20.0 points in the surgery group and 14.4 points in the rehabilitation group. Mean difference in favor of surgery on secondary outcomes were 9.9 points on VAS and 0.16 points on HSCL-25. There were 18 patients (24%) in the surgery group and 4 patients (6%) in the rehabilitation group who reported full recovery. There were no significant differences between the groups in EQ-5D, occupational status, satisfaction with care, or drug use. Forty-three of 61 patients (70%) in the surgery group and 26 of 52 patients (50%) in the rehabilitation group had a clinically important improvement (15 ODI points or more) from baseline. Twenty-one patients (24%) randomized to rehabilitation had crossed over and had undergone back surgery and 12 patients (14%) randomized to surgery had undergone additional back surgery. One serious adverse event after disc replacement was reported. The authors concluded that long-term improvement can be expected after both disc replacement and MDR. The difference between groups is statistically significant in favor of surgery, but smaller than the prespecified clinically important difference of 10 ODI points that the study was designed to detect. Future research should aim to improve selection criteria for disc replacement and MDR.

A prospective, multicenter, randomized, controlled, investigational device exemption study with 5-year follow-up was conducted by Yue and Garcia (2017) to compare the safety and effectiveness of lumbar total disc replacement with activL (Test group) or ProDisc-L or Charité (Control group) in the treatment of patients with symptomatic, single-level degenerative disc disease. Patients who failed at least 6 months of nonsurgical management were randomly allocated to treatment with the Test device (n=218) or Control devices (n=106). At 5-year follow-up, 185 Test patients and 90 Control patients provided 5-year follow-up data. Device effectiveness outcomes were comparable between Test and Control devices. Reductions in back pain severity were reported in 88% of Test patients and 90% of Control patients. Oswestry Disability Index (ODI) improvement was reported in 83% and 86% of patients, respectively. Patient satisfaction was very high in both groups (96% vs 94%). No significant differences were observed between groups in radiographic outcomes, including disc height, disc angle, flexion-extension ROM, translation ROM, and lateral rotation. Lack of a serious adverse event through 5 years was 58% in Test patients and 40% in Control patients. The authors concluded that total disc replacement is safe and effective for the treatment of symptomatic lumbar degenerative disc disease and is maintained through 5 years.

A prospective observational cohort study was conducted by Laugesen et al. (2017) to determine the long-term clinical results and prosthesis survival in patients treated with lumbar total disc replacement (TDR). Fifty-seven consecutive patients treated with TDR from 2003 to 2008 were invited to follow-up at a mean 10.6 years post-operatively and complete a Visual Analog Scale (VAS) for back and leg pain, the Dallas Pain Questionnaire (DPQ), and the Short Form-36. These surveys were also administered to the subjects before their index TDRs. Data on reoperation were collected from the patients' medical records. The authors report that there was a significant improvement in VAS and DPQ in the entire cohort. Nineteen patients (33%) had a revision fusion surgery after their index TDR. Patients who had revision surgery had statistically significant worse outcome scores at last follow-up than patients who had no revision. Thirty patients (52.6%) would choose the same treatment again if they were faced with the same problem. The authors concluded that this study demonstrated significant improvement in long-term clinical outcomes and two-thirds of the discus prostheses were still functioning at follow-up. They also acknowledge that there is still a lack of well-designed long-term studies, thus requiring further investigation.

A systematic review and meta-analysis was performed by Lackey et al. (2016) to assess the effect of hybrid constructs which involve a total disc arthroplasty (TDA) with stand-alone anterior lumbar interbody fusion (ALIF) versus non-hybrid constructs including posterior transpedicular fixation or multi-level stand-alone ALIF as a surgical intervention for degenerative disc disease (DDD) in the lumbar spine. Primary outcomes analyzed included the Oswestry Disability Index (ODI) and the Visual Analogue

Scale (VAS) for back pain. Three studies met inclusion criteria. When comparing hybrid constructs to multi-level TDA or lumbar fusion (LF) improvements in back pain were found with a VAS back pain score reduction of 1.38 postoperatively and a VAS back pain score reduction of 0.99 points at 2-years follow-up. Current results slightly favor clinically significant improved VAS back pain score outcomes postoperatively and at 2-years follow-up for hybrid constructs in multi-level lumbar DDD of the spine when compared with non-hybrid multi-level LF or TDA. The authors stated that it cannot be concluded that a hybrid construct is superior to multi-level LF or TDA based on this meta-analysis and recommend further prospective studies to delineate best practice in the management of degenerative disc disease of the lumbar spine.

Pimenta et al. (2016) conducted a prospective nonrandomized single-center study to analyze results of XL-TDR for the treatment of symptomatic degenerative disc disease. Sixty cases were enrolled. Eleven of 60 patients (18%) had not completed at least a 5-year follow-up (FUP), and 49 were enrolled in the analysis. The mean FUP was 93 months. End points included visual analog scale (VAS) and Oswestry Disability Index (ODI) questionnaires, radiographic outcomes (radiographs and CT) such as heterotopic ossification (HO) and maintenance of disc motion, complications, reoperation, and heterotopic ossification grades. All but 3 patients stood up/walked at the same day. Five levels (10%; 5/53) required fusion. Two cases (4%; 2/49) evolved with adjacent level disease that required surgery. One case required sacroiliac fusion. One partial disc migration was identified. Flexion-extension films from 38 levels were available at least at a 5-year FUP. HO grade 0 = 13%; grade I = 18%; grade II = 32%; grade III = 16%; grade IV = 21% (8 cases). Most heterotopic ossification cases (85%) occurred in the lateral aspect of the disc space. Patient-reported outcomes showed significant improvement maintained up to a minimum of 5 years. VAS back pain: preoperative 8.5, postoperative early 2.5, and last FUP 3.0. ODI: preoperative 54%, postoperative early 31%, and last FUP 21%. The authors concluded that the data show satisfactory sustained pain relief and improved physical function for the patients and lumbar artificial disc replacement done by the lateral approach seems to be a feasible effective treatment for mild degenerative disc disease. Further research with larger randomized controlled trials is needed to validate these findings.

Garcia et al. (2015) conducted a prospective, multicenter, randomized, controlled, investigational device exemption (IDE) trial to evaluate the comparative safety and effectiveness of lumbar total disc replacement (TDR) in the treatment of patients with symptomatic degenerative disc disease (DDD) who are unresponsive to nonsurgical therapy. The study consisted of patients presenting with symptomatic single-level lumbar DDD who failed at least 6 months of nonsurgical management. They were randomly assigned to treatment with an investigational TDR device (activL[®], n = 218) or FDA-approved control TDR devices (ProDisc-L[®] or Charité[®], n = 106). Patient satisfaction with treatment was over 90% in both groups at 2 years. Back pain severity improved 74% with activL[®] and 68% with controls. Oswestry Disability Index (ODI) improved 67% with activL[®] and 61% with controls and Physical Component Summary score (88% vs. 81%) favored the activL[®] group. The percentage of patients working full-time with no restrictions increased from 33% at pretreatment to 57% at 2 years with activL[®] and from 33% to 49% with control. Return to work was approximately 1 month shorter with activL[®] versus controls. The percentage of patients with disc height increase >3mm was 94% with activL[®] and 87% with controls. Change in range of motion in lateral flexion-extension radiographs was statistically greater with activL[®] compared with controls in segmental rotation and translation but not in lateral rotation on side-bending radiographs. The rate of device-related serious adverse events was lower in patients treated with activL[®] versus controls (12% vs. 19%). Surgical reintervention rates were comparable (activL 2.3%, control 1.9%). The authors concluded that the single-level activL[®] TDR is safe and effective for the treatment of symptomatic lumbar DDD through 2 years. The long-term durability of the activL[®] TDR is unknown and requires further investigation.

Park et al. (2015) conducted a retrospective analysis to evaluate successful outcomes following lumbar total disc replacement (TDR) using ProDisc[®] II on 54 patients (81 segments) between March 2002 and February 2007. Data was reviewed at 1, 2, 5 and 7 year follow-up. Clinical outcomes were evaluated using Visual Analog Scale (VAS), Oswestry Disability Index (ODI), and subjective satisfaction (4-point scale). Radiographic results included segmental range of motion (ROM). Total VAS scores decreased significantly at postoperative 1 year and 2 year, compared with preoperative VAS score. Although total VAS scores increased until the last follow-up, they remained significantly lower than the preoperative value. All postoperative ODI scores at any follow-up time were significantly lower than the baseline value. There was significant increase in ODI scores between 2-year and last follow-up. The final range of motion (ROM) was shown to be lower than the preoperative ROM and lumbar lordosis was increased and well-maintained during all postoperative follow-up times. Five patients (9.3%) required revision fusion surgeries.

An August 2015 Hayes Medical Technology assessment evaluated 7 randomized controlled trials (RCTs), 1 nonrandomized trial, and 6 uncontrolled studies with long-term (7 to 17 years) results published between 2002 through July 2015. A total of 2882 patients who underwent one or two level disc replacement treatment were included. The findings suggest that 1-level lumbar disc replacement (LDR) is comparable in efficacy and safety to fusion for the treatment of symptomatic degenerative disc disease in selected patients who have failed conservative treatment. Questions remain regarding the long-term safety of

lumbar disc replacement and there is insufficient evidence comparing LDR with continued treatment with more conservative nonsurgical treatment options.

A July 2017 updated cumulative literature search retrieved eight abstracts, including 2 prospective randomized trials (RCTs); 1 follow-up to a multicenter randomized controlled trial; 1 prospective nonrandomized single-center study; 1 comparison study; 1 prospective observational cohort study; 1 systematic review and meta-analysis; and 1 systematic review. The available RCTs provided moderate-quality evidence that 1-level lumbar total disc replacement (LTDR) is comparable to fusion for the treatment of symptomatic degenerative disc disease (DDD) in highly selected patients who have failed conservative treatment. They found insufficient evidence to determine whether motion preservation with LTDR will prevent symptomatic adjacent segment DDD. There was insufficient evidence investigating LTDR for the treatment of 2-level DDD. The report concluded that further longer-term follow-up studies are required to determine whether LTDR poses any additional risk compared with fusion beyond 5 years.

A Cochrane review (Jacobs, et al., 2012) was conducted to determine how total disc replacement compared with other treatments for chronic low back pain. The review included seven randomized trials involving 1474 subjects in total, and involved the use of four discs: Charite[®], Maverick[®], Prodisc-L[®], and Flexicore[®]. Six of the trials compared disc replacement to lumbar fusion and one compared disc replacement to nonsurgical treatment consisting of a rehabilitation protocol with cognitive treatment and physical therapy. Follow-up was 24 months in all studies with the exception of one which was five years. The subjects who had disc replacement surgery had slightly better back pain and function outcome scores compared to those who had fusion surgery; the differences did not appear clinically significant. The studies did not demonstrate any other benefit and did not provide any information regarding long-term risks. As a result, the review concluded the spine surgery community should be cautious with regards to adopting the technology on a large scale; long-term outcomes are lacking. Pain relief outcomes are short-term and studies evaluating adjacent segment degeneration and facet joint degeneration are lacking.

In 2011 Delamarter et al. published the results of a prospective randomized multicenter FDA IDE trial evaluating the ProDisc-L[®] compared to circumferential fusion for two-level DDD. Reported outcomes included patient self-assessments, physical, neurological and radiograph assessment pre-operatively and six weeks, three, six, twelve, eighteen and twenty-four months postoperatively. Although ODI scores significantly improved in both groups from preoperative to postoperative, results were significantly better in the total disc group). A significant reduction in narcotic usage was also reported for the disc group. In the authors opinion two-level lumbar disc replacement using the ProDisc-L[®] device was a viable alternative to lumbar arthrodesis for the treatment of two-level disc disease.

Kim et al. (2007) completed a prospective controlled study of 32 patients who underwent lumbar total disc replacement using the ProDisc[®] II prosthesis. Patients were monitored for 24 months. Nineteen patients had single level total disc replacements (TDR), while 11 patients had TDR at two levels. Radiographic documentation of each patient's range of motion (ROM) was obtained prior to and every 6 months following TDR. Differences between these measures were compared and the outcomes were reported using degrees as a control measure. Visual analog and disability indexes improved significantly during the follow up period. ROM improved within the first 6 months at levels L3-4 and L4-5 being noted. ROM decreased following TDR at the L5-S1 level, with no significant improvement noted at any time. The level of the TDR was found to be a potential negative factor in the minimal gains that were achieved in ROM.

A retrospective study by Yaszay et al. (2008) of 42 patients enrolled in a prospective randomized FDA ProDisc[®]-L trial, were analyzed to determine factors that could influence motion and patient satisfaction following total disc replacement (TDR) at L4/5 or L5/S1. The patients selected received a TDR at L4/5 or L5-S1. Pre- and postoperative disc height and range of motion (ROM) were measured from standing lateral and flexion-extension radiographs. Anterior and posterior disc heights increased; however, the patients' ROM had decreased. Threshold factors (i.e., anterior and posterior disc heights) that were analyzed showed patients with <9 mm of anterior disc height had an increased ROM of 2.2° of disc height had a -2.2 decrease in their ROM. These findings were considered significant. While improvements were noted based on patient reported visual analog scale scores and Oswestry Disability Index measures, no significant difference between the groups could be found that would explain the average decrease in ROM from 7.0° to 5.7° patients following the use of TDR will determine if the ROM gains will be maintained.

In 2009 the National Institute for Health and Care Excellence (NICE) concluded that the current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support its use in the lumbar spine. They recommend specialist with expertise in the treatment of degenerative spine disease should be involved in patient

selection and the procedures should only be carried out in patients for whom conservative treatment options have failed or are contraindicated.

Professional Societies

American Pain Society

Guidelines from the American Pain Society (Chou 2007) found insufficient evidence regarding long-term benefits 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 fusion rates, but it is not known if instrumentation improves clinical outcomes. More research with longer follow-up is needed to determine the appropriate role of artificial disc replacement versus fusion. The authors suggest that vertebral fusion be performed for patients who undergo surgical intervention for chronic low back pain.

International Society for the Advancement of Spine Surgery (ISASS)

A 2015 ISASS Policy Statement states that there is sufficient evidence-based scientific evidence to support the safety and efficacy of single level lumbar total disc replacement for patients meeting well established selection criteria.

Inclusion criteria include:

- Skeletally mature patients with degenerative disc disease (DDD) at one level from L3-S1
- Patients should have no more than Grade 1 spondylolisthesis at the involved level
- Patients failed at least six months of conservative treatment prior to implantation

North American Spine Society (NASS)

A 2019 NASS Coverage Policy Recommendation states that lumbar artificial disc replacement is indicated for patients with discogenic low back pain who meet all of the following criteria:

- Symptomatic single level lumbar disc disease at L3-L4, L4-L5 or L5-S1 level
- Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period that should include a physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs
- Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention
- Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Lumbar

The following lumbar disc replacement products (product code MJO) have received FDA approval:

- The activL[®] Artificial Disc (Aesculap Implant Systems, LLC) received FDA Premarket Approval on June 11, 2015. It is indicated for people who have fully formed and fully grown bones (are skeletally mature), have low back pain due to a problem with one lumbar disc (as determined by a doctor), have been diagnosed as having degenerative disc disease (DDD) in only one lumbar disc at either level L4/L5 or L5/S1 (as determined by a doctor), and have gone through at least six months of non-surgical treatment without relief. The device is designed to help stabilize the operated spinal level and allow motion at the level. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120024A.pdf. (Accessed May 10, 2019)
- The Charite[®] intervertebral disc (DePuy Spine, Inc., Raynham, MA) received FDA Premarket Approval on October 26, 2004. It is approved for use in patients who have single-level degenerative disc disease (L4-S1) of the lumbar spine and who have had no relief from low back pain after at least six months of nonsurgical treatment. Removed from the market in 2012.
- The ProDisc-L[®] Total Disc Replacement received FDA Premarket Approval on August 14, 2006 for use in patients who have single-level degenerative disc disease of the lumbar spine (L3-S1) and who have had no relief from low-back pain after at least 6 months of nonsurgical treatment. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010A.pdf. (Accessed May 10, 2019)

Cervical

The following cervical disc replacement products (product code MJO) have received FDA approval:

- M6-C™ Artificial Cervical Disc Prosthesis received premarket approval on February 6, 2019 (P170036). The M6 has two titanium outer plates with keels for anchoring the disc into the bone of the vertebral body. These outer plates are coated with a titanium plasma spray that promotes bone growth into the metal plates, providing long term fixation and stability of the disc in the bone. The M6-C™ Artificial Cervical Disc is indicated for reconstruction of the disc following single level discectomy in skeletally mature patients with intractable degenerative cervical radiculopathy with or without spinal cord compression at one level from C3–C7. Degenerative cervical radiculopathy is defined as arm pain and/or a neurological deficit (numbness, weakness, deep tendon reflexes changes) with or without neck pain due to disc herniation and/or osteophyte formation and confirmed by radiographic imaging (CT, MRI, x-rays). The M6-C™ Artificial Cervical Disc is implanted via an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or exhibit progressive neurological symptoms which could lead to permanent impairment prior to implantation of the M6-C™ Artificial Cervical Disc. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/p170036a.pdf. (Accessed May 10, 2019)
- Mobi-C® Cervical Disc Prosthesis received premarket approval on August 7, 2013. (P110002). The Mobi-C® Cervical Disc Prosthesis consists of two metal (cobalt-chrome alloy 2) endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (cervical vertebrae) to replace a diseased cervical disc that is causing arm pain and/or weakness or numbness. The Mobi-C® Cervical Disc Prosthesis is intended for skeletally mature patients (people who have stopped growing) to replace a cervical disc in the neck (from C3-C7) following removal of the disc for conditions that result from a diseased or bulging disc at only one spinal level. The device should help stabilize the operated spinal level. Unlike a fusion procedure, the Mobi-C® Cervical Disc Prosthesis is designed to allow motion at the operated spinal level. The effects of the diseased disc removal should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110002a.pdf. (Accessed May 10, 2019)
- Mobi-C® Cervical Disc Prosthesis (two-level) received premarket approval of August 23, 2013. (P110009). The Mobi-C® Cervical Disc Prosthesis consists of two metals (cobalt-chrome endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (cervical vertebrae) to replace a diseased cervical disc at two adjacent levels that are causing arm pain and/or weakness or numbness. The Mobi-C® Cervical Disc Prosthesis is intended for skeletally mature patients (people who have stopped growing) to replace two adjacent cervical discs in the neck (from C3-C7) following removal of the discs for conditions that result from diseased or bulging discs at two adjacent spinal levels. The two devices should help stabilize the operated spinal levels. Unlike a fusion procedure the Mobi-C® Cervical Disc Prosthesis is designed to allow motion at the operated spinal levels. The effects of removing the diseased discs should include pain relief and improved function. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110009a.pdf. (Accessed May 10, 2019)
- ProDisc-C® Total Disc Replacement received premarket approval on December 17, 2007 (P070001). The device is indicated for skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable symptomatic cervical disc disease (SCDD). Symptomatic cervical disc disease is 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): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes) and/or loss of disc height. The ProDisc-C® total disc replacement is implanted via an open anterior approach. Patients receiving the ProDisc-C® total disc replacement should have failed at least six weeks of non-operative treatment prior to implantation. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070001a.pdf. (Accessed May 10, 2019)
- Prestige® LP Cervical Disc received premarket approval on July 24, 2014. Indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, x-ray): herniated nucleus pulposus, spondylosis (defined by the presence of osteophytes), and/or visible loss of disc height as compared to adjacent levels. In July 2016, the Prestige® LP received FDA approval for implantation at 2 levels. Additional information is available at: https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090029c.pdf. (Accessed May 10, 2019)
- Prestige® Cervical Disc System received premarket approval on July 16, 2007 (P060018). The device is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The PRESTIGE® device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2)

osteophyte formation. The safety and effectiveness of the device has not been established in patients who have not undergone at least six weeks of conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care. Additional information is available at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P060018>. (Accessed May 10, 2019)

- Bryan® Cervical Disc received premarket approval on May 12, 2009 (P060023). The device is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The Bryan® device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy is defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy or spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT and/or magnetic resonance imaging (MRI). Patients receiving the Bryan® Cervical Disc should have failed at least six weeks of non-operative treatment prior to implantation. Additional information is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P060023>. (Accessed May 10, 2019)
- SECURE®-C Artificial Cervical Disc received premarket approval on September 28, 2012 (P100003). The SECURE®-C Artificial Cervical Disc is intended to be used in skeletally mature patients (people who have stopped growing) to replace a cervical disc in the neck (from C3-C7) following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy³ or myelopathy⁴) at only one level. The device should help stabilize the operated disc in the neck. Unlike a fusion procedure⁵, the SECURE®-C Artificial Cervical Disc is designed to allow motion at the operated disc. The effects of the diseased disc removal should include pain relief and improved function. Additional information is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100003>. (Accessed May 10, 2019)
- PCM® Cervical Disc System received premarket approval on October 26, 2012 (P100012). The PCM Cervical Disc consists of two metal (cobalt-chrome alloy) endplates and a plastic (ultra-high molecular weight polyethylene) insert that fits between the endplates. The device is placed between two adjacent neck bones (vertebrae) to replace a diseased cervical disc² that is causing arm pain and/or weakness or numbness. The PCM Cervical Disc is intended to be used in skeletally mature patients (people who have stopped growing) to replace a cervical disc from C3-C7 following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy³ or myelopathy⁴) at only one level. The device should help stabilize the operated disc in the neck (spinal level). Unlike a fusion procedure⁵, the PCM Cervical Disc is designed to allow motion at the operated spinal level. The effects of the diseased disc removal should include pain relief and improved function. Additional information is available at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100012>. (Accessed May 10, 2019)

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Policy History/Revision Information

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none"> • Removed <i>Related Policies</i> and <i>CMS</i> sections • Updated <i>Instructions for Use</i>; replaced reference to “MCG™ Care Guidelines” with “InterQual® criteria”
02/01/2021	Template Update <ul style="list-style-type: none"> • Reformatted policy; transferred content to new template
12/09/2020	<ul style="list-style-type: none"> • Corrected typographical error; added language to clarify lumbar artificial total disc replacement is unproven and not medically necessary
05/01/2020	Coverage Rationale <ul style="list-style-type: none"> • Revised proven and medically necessary criteria for lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc: <ul style="list-style-type: none"> ○ Added criterion requiring “favorable psychosocial-behavioral evaluation to be conducted by an individual who is professionally recognized as part of a behavioral health discipline to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome” ○ Removed criterion requiring “favorable face-to-face psychological evaluation confirming candidacy for surgery” Supporting Information <ul style="list-style-type: none"> • Archived previous policy version CS121LA.J

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.