Regence

Medical Policy Manual Surgery, Policy No. 127

Artificial Intervertebral Disc

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Artificial intervertebral discs, also known as intervertebral disc prostheses, are synthetic replacements for damaged intervertebral discs in the cervical or lumbar regions of the spine.

MEDICAL POLICY CRITERIA

Note: This policy does not address revision or replacement of artificial intervertebral discs.

I. Anterior total cervical disc replacement with or without hybrid construct following complete decompression is considered **medically necessary** in patients with symptomatic cervical disc degeneration when ***all*** of the following criteria (A-G) are met:

   A. Request is for an FDA-approved artificial intervertebral disc; and

   B. Request is for a single level or simultaneous two contiguous level replacement; and

   C. The patient is skeletally mature; and

   D. Disc replacement is limited to levels between C3 and C7; and

   E. Diagnosis of cervical radiculopathy or myelopathy with radicular arm pain and neurological deficit in a specific nerve root distribution or myelopathic level

consistent with the neuroimaging and the operative cervical spinal level when *at least one* of the following criteria are met:

1. There is clinical documentation that a minimum of six weeks of conservative nonoperative therapy failed to adequately treat the patient's symptoms, including *at least two* of the following therapies:
    a. Use of narcotic or nonnarcotic analgesics, and/or nonsteroidal anti-inflammatory drugs (NSAIDs), if not contraindicated; or
    b. A trial of physical therapy; or
    c. Alteration of activities, including but not limited to cessation of activities that exacerbate symptoms; or
2. Severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring immediate surgical treatment (e.g., increasing numbness/tingling; increasing motor loss or less than or equal to 3/5 muscle strength).

F. Documented findings on MRI, CT, or other imaging must meet the following:

1. Imaging is consistent with the patient's symptoms and demonstrate moderate to severe spinal stenosis, cord compression, or nerve root compression from *at least one* of the following at the operative level (If requesting a second level disc replacement, imaging must be within six months.):
    a. Herniated disc; or
    b. Spondylosis, defined as the presence of osteophytes; and

G. The patient is an appropriate candidate for anterior cervical spinal surgery, including *absence of all* of the following contraindications (1-4):

1. Prior surgery at the operative levels; and
2. Prior cervical artificial disc replacement at two or more levels; and
3. Radiographic confirmation of severe facet joint pathology of involved vertebral bodies; and
4. Concomitant conditions known to affect osteogenesis including any of the following:
    a. Metabolic bone disease (e.g., gout, osteoporosis [T-score less than or equal to -2.5 by DXA], osteomalacia, Paget's disease); or
    b. Current or past history of primary or metastatic spinal malignancy; or
    c. Conditions requiring daily high-dose oral steroids (e.g., rheumatoid arthritis).

II. Subsequent, second-level, anterior total cervical disc replacement following complete decompression may be considered **medically necessary** in patients with symptomatic cervical disc degeneration when *all* of the following (A-E) are met:

A. Request is for an FDA-approved artificial intervertebral disc; and

B. The patient is skeletally mature; and

C. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement; and

D. Clinical documentation that the initial cervical artificial disc replacement is fully healed; and

E. Criteria I.A-G. are met.

III. Total lumbar disc replacement may be considered **medically necessary** when all of the following are met:

A. Request is for an FDA-approved artificial intervertebral disc: and

B. Request is for a single level replacement at L3-4, L4-5, or L5-S1; and

C. Individual is age 18-60 years old; and

D. Individual has symptomatic single level discogenic low back pain; and

E. Procedure does not include a planned simultaneous fusion (hybrid surgery) at an adjacent lumbar level; and

F. Findings on MRI, CT, or other imaging demonstrate all of the following:

1. Moderate to severe single-level disc degeneration at the operative level; and
2. Absence of degenerative disc disease at more than one level; and
3. Absence of degenerative disc disease above L3-L4; and

G. There is clinical documentation that a minimum of six weeks of conservative nonoperative therapy failed to adequately treat the patient's symptoms, including *at least two* of the following therapies:

1. Use of narcotic or nonnarcotic analgesics, and/or nonsteroidal anti-inflammatory drugs (NSAIDs), if not contraindicated; or
2. A trial of physical therapy; or
3. Alteration of activities, including but not limited to cessation of activities that exacerbate symptoms; and

H. Absence of all of the following contraindications:

1. Procedure performed for revision of a failed lumbar artificial total disc arthroplasty; and
2. Facet ankylosis or severe facet degeneration at the operative level; and
3. Individual has osteopenia or osteoporosis; and
4. Imaging findings demonstrating any of the following:
    a. Degenerative or lytic spondylolisthesis > 3mm; or
    b. Lumbar spinal stenosis; or
    c. Pars interarticularis defect with spondylolysis or isthmic spondylolisthesis; or
    d. Lumbar scoliosis defined as greater than 11 degrees of sagittal plane deformity; or

e. Spinal fracture; or

f. Presence of tumor or active infection at the site of implantation; or

g. Lumbar nerve root compression or bony spinal stenosis; or

h. Preoperative remaining disc height of <3mm; or

i. Mid-sagittal stenosis of <8mm; and

5. History of ankylosing spondylitis, rheumatoid arthritis, lupus, or other autoimmune disorder; and

6. Isolated radicular compression syndromes.

IV. Total cervical disc replacement that does not meet Criterion I. or II. is considered **not medically necessary**.

V. Total lumbar disc replacement that does not meet Criterion III. is considered **not medically necessary**.

VI. Total disc replacement with artificial intervertebral discs is considered **investigational** for all other indications.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

Hybrid surgery is defined as surgery containing elements of traditional discectomy and fusion, artificial disc replacement, and anterior cervical corpectomy and fusion in varying proportions.

LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Documentation of symptoms and associated diagnoses
- MRI, CT or other imaging completed with documented findings
- Documented level(s) of planned artificial intervertebral disc placement
- Documentation of conservative nonoperative therapy completed and symptom response
- Specific name of device being requested

CROSS REFERENCES

1. Percutaneous Intradiscal Electrothermal Annuloplasty (IDET) and Percutaneous Intradiscal Radiofrequency Thermocoagulation, Surgery, Policy No. 118
2. Total Facet Arthroplasty, Surgery, Policy No. 171
3. Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis, Surgery, Policy No. 176
4. Lumbar Spinal Fusion, Surgery, Policy No. 187

BACKGROUND

Artificial intervertebral discs are being studied as a motion-preserving alternative to spinal

fusion. There are a number of artificial cervical and lumbar discs that are under investigation, some of which have received approval for marketing from the U.S. Food and Drug Administration (FDA). FDA product code: MJO. Please see the table below for a list of artificial discs. Note: The table is arranged in alphabetical order by device name. Some manufacturers have multiple devices. An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. All clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated.

Artificial Cervical Discs		
Device	Manufacturer	FDA Approval
Advent®	Orthofix®	No
BRYAN® disc	Medtronic	Yes – single level
Cadisc™-C	Rainier® Technology	No
Cervicore (metal on metal-cobalt-chromium-molybdenum)	Stryker	No IDE status revoked by FDA
Discover™ (polyethylene on titanium alloy)	DePuy Synthes (formerly DePuy Spine, Inc.)	No IDE only
Freedom® Cervical Disc	AxioMed®	No
Kineflex®-C (cobalt-chromium-molybdenum)	SpinalMotion	No IDE only
M6®-C	Spinal Kinetics™	Yes- single level
Mobi-C®	LDR Spine USA	Yes – single- and two-level
NeoDisc®	NuVasive®	No IDE only
PCM® (Porous Coated Motion) Cervical Disc (polyethylene-on-metal)	Cervitech, now part of NuVasive®	Yes – single level
Prestige® Cervical Disc System (includes Prestige ST) (titanium-ceramic)	Medtronic	Yes – single level
Prestige®-LP Cervical Disc	Medtronic	Yes – single and two-level
ProDisc®-C	DePuy Synthes	Yes – single- and two level
SECURE®-C	Globus Medical	Yes – single level
Simplify Cervical Artificial Disc	Simplify Medical, now part of NuVasive®	Yes – single and two-level

Artificial Lumbar Discs		
Device	Manufacturer	FDA Approval
Activ-L™	Aesculap®	Yes – single level

Artificial Lumbar Discs		
Device	Manufacturer	FDA Approval
Cadisc™-L	Rainier® Technology	No
~~Charité®~~	~~DePuy Spine, Inc.~~	- Withdrawn from the market
FlexiCore®	Stryker	No
Freedom® Lumbar Disc (FLD)	AxioMed®	No
INMOTION® (formerly Charité®)	Depuy Spine™	Yes – single level. This device is a modification of the Charité design
Kineflex-L™ metal-on-metal implant	SpinalMotion	No
M6®-L	Spinal Kinetics™	No
Maverick®	Medtronic	No
ProDisc®-L	DePuy Synthes (formerly Synthes Spine)	Yes – single level
XL TDR®	NuVasive®	No

EVIDENCE SUMMARY

Evaluating the safety and effectiveness of total disc replacement with artificial intervertebral discs (TDR) requires randomized controlled comparisons with fusion, which is the current standard for surgical treatment of degenerative disc disease (DDD). Randomization is necessary in evaluating any treatment in which improvements in pain and function are the most clinically relevant outcomes. Pain is a subjective outcome and can be influenced by nonspecific effects (e.g., placebo response, the natural history of the disease, and the severity of the condition). Consequently, any difference in the outcome observed between the study groups may, with reasonable assuredness, be attributed to the treatment under investigation. Studies must include sufficient numbers of participants in order to eliminate the element of chance as an explanation of study outcomes, and to allow generalization of results. Postoperative follow-up of at least five years is recommended to assess the long-term effects of TDR on overall health outcomes.

CERVICAL DISC

SYSTEMATIC REVIEWS

Wang (2020) published a systematic review including 11 randomized controlled trials with 3505 patients evaluating the long-term results of cervical disc arthroplasty (CDA) compared to anterior cervical discectomy and fusion (ACDF).[1] All the studies that were included were rated to have a low risk of bias by the authors. Overall clinical, NDI, and neurological success rates were superior for patients receiving CDA compared to ACDF. Additionally, functional outcomes such as Visual Analog Scale scores for neck and arm pain and total secondary surgeries were shown to be superior in the patients who received CDA. There was no significant difference in total report adverse events between the two groups. The authors concluded that there is evidence that CDA is superior in reaching long-term clinical success compared to ACDF and additional long-term randomized trials are necessary for further evaluating some outcomes.

Similar findings were reported by Deng (2020) in a meta-analysis of nine studies with 48 to 120 months of follow-up.[2] Symptomatic adjacent-level disease requiring surgery was significantly lower following cervical disc arthroplasty compared to anterior cervical discectomy and fusion. An additional study by Toci that included 19 studies also demonstrated CDA had significantly lower adjacent segment pathologies and reoperation rates.[3]

PRESTIGE ST AND PRESTIGE LP CERVICAL DISC

Prestige ST

The Prestige disc received FDA marketing approval in 2007. Information on the Prestige cervical disc is available from a published report of the pivotal trial and from Medtronic's premarket approval (PMA) application to FDA.[4, 5] These documents report resulted from a randomized study comparing anterior cervical fusion (with allograft bone and plate stabilization) to the artificial cervical disc for patients with nonaxial pain and other symptoms secondary to radiculopathy or myelopathy that had not improved over a minimum six weeks of conservative therapy. The study was designed as a randomized, nonblinded noninferiority trial with a 10% margin. Results for 137 investigational and 148 control patients evaluated at two years postsurgery were presented to FDA in the PMA application. These patients represented about half of the total population (276 and 265, respectively), while the peer-reviewed article reported on about 75% of cases.

Three primary outcome variables were used in the Prestige pivotal trial: the NDI score, neurologic status, and functional spinal unit (FSU) height. The NDI is a validated multidimensional instrument that measures the effects of pain and disability on a patient's ability to manage everyday life.[6] It is a modification of the Oswestry Disability Index (ODI), based on the response to 10 questions that focus on neck pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Responses to each question range from 1 to 5, with a lower numeric score representing a better pain and disability status for that variable. A total NDI score is obtained by adding individual question scores and dividing by the maximum total of 50, if all questions are answered. Therefore, NDI scores range from 0% to 100%, with a lower percentage indicating less pain and disability. Neurologic status is a composite measure of motor function, sensory function, and deep tendon reflexes. It is used to judge if patients are within normal parameters for those categories based on physiologic measurement. Neurologic success in the Prestige trial was based on postoperative maintenance or improvement of condition compared with preoperative status for each component. The anterior FSU height is a radiographic measure of interdiscal space. Comparison of the immediate postoperative FSU height with the six-week postoperative value shows whether the disc space has decreased, which indicates that graft or device subsidence has occurred. Secondary outcome measures include the 36-Item Short-Form Health Survey (SF-36) Mental (MCS) and Physical Component Summary (PCS) scores, neck and arm pain status, patient satisfaction, patient global perceived effect, gait assessment, foraminal compression test, adjacent-level stability and measurements, return to work, and physician's perception.

Both data sources for the Prestige disc trial showed equivalent results. Thus, 81% of both groups showed at least a 15-point improvement for the NDI, demonstrating noninferiority to fusion but not superiority. Similarly, the FSU height measure also demonstrated evidence of noninferiority but not superiority. Neurologic status showed noninferiority and statistical superiority for the disc compared with fusion. This contributed to the overall success composite

end point demonstrating superiority for the disc compared with fusion. While maintained or improved neurologic status was more frequent following AIDA, it was unclear whether examiners were blinded. Most secondary outcome measures for the disc were deemed noninferior to anterior cervical discectomy and fusion (ACDF), but none was statistically superior. Perioperative results and adverse events (AEs) were similar in both groups, with very few serious complications.

Five-year and seven-year follow-ups of participants in this clinical trial were reported by Burkus in 2010 and 2014, respectively.[7, 8] All participants were followed in this FDA-regulated postapproval study. Outcomes at 60 months were reported on approximately half of the original RCT participants. Patients who had not yet reached that point in their follow-up for the 2010 publication were included in the 2014 report. Follow-up at 84 months was obtained in 73% of study participants (212 AIDA, 183 ACDF). Overall success rates at 78 months were 72.6% for the Prestige disc and 60.0% for ACDF (p=0.008), NDI scores improved by 37.5 points for the Prestige disc compared with 31.9 points for ACDF (p=0.002), and neurologic success was greater in the Prestige disc group (88.2% vs 79.7%, p=0.011). There was no significant difference between the 2 groups in NDI success rates at 84 months (p=0.109) or in work status. The rate of secondary surgeries at the initial treatment level was lower for Prestige (4.8%) than for ACDF (13.7%; p<0.001), but there was no significant difference in the rate of adjacent-level surgeries (3.9% vs 5.4%).

Single-level Prestige LP

Twenty-four-month results from the pivotal trial for the Prestige LP disc were published in 2015.[9] This multicenter noninferiority trial compared 280 patients who received the Prestige LP disc to 265 historical ACDF controls from the Prestige IDE study described above. Primary outcomes were neurologic success, individual success, and overall success. Blood loss and hospital stay were similar between groups, but median return-to-work time was significantly shorter for the Prestige LP group (40 days) than the ACDF group (60 days; p=0.020). With a rate of follow-up at 24 months of 97.1% for the Prestige LP group and 84.0% for controls (excluding radiographic assessment of disc height), noninferiority was demonstrated. Neurologic success was superior in the Prestige LP group (93.5%) compared to the control group (83.5%), with a Bayesian probability of ≈1.00. Superiority on the composite measure of overall success was supported with a Bayesian probability of 0.994. In addition to statistical analysis by the study sponsor, raw data were provided to Vanderbilt University for independent confirmation of results.

Two-Level Prestige LP

In July 2016, the Prestige LP received FDA approval for implantation at two levels. Approval was based on 24-month data from a noninferiority trial that randomized patients to AIDA (n=209) or ACDF (n=188) at two contiguous levels.[10] Data for FDA approval were collected until the last subject enrolled had completed 24-month follow-up. Additional prespecified evaluations are scheduled at 36, 60, 84, and 120 months. The primary outcome was overall success, defined as a 15-point improvement on the NDI, maintenance or improvement in neurologic status, no serious AE classified as implant or surgery related, and no additional surgical procedure classified as a failure, with a noninferiority margin of 10%. Secondary outcomes include the improvement in NDI score, improvement in neck and arm pain, improvement in quality of life, subject satisfaction, medication usage, range of motion, HO, and work status compared to the two-level ACDF group.

Complete overall success data at 24 months were available for 199 (95.2%) two-level Prestige LP patients and 160 (88.9%) ACDF controls. Overall success was achieved in 81.4% of Prestige LP patients and in 69.4% of ACDF controls, meeting both noninferiority and superiority with a posterior probability of near 100% and 99.3%, respectively. The average difference in the chance of success between the two-level Prestige LP group and the two-level ACDF group at 24 months was 11.3%, with a 95% probability that this difference falls in the range of 2.2% to 20.1%. Based on Bayesian credible intervals (CrI), there were no statistical differences between the two treatment groups for adverse events. There were 12 (6.4%) severe device-related adverse events in the two-level ACDF group compared to five (2.4%) in the Prestige LP group. More patients in the two-level ACDF group underwent subsequent surgical procedures at the index level (8.0%) than in the Prestige LP group (2.4%) (posterior mean, -5.6%; 95% CrI, -10.2% to -1.1%).

The difference in success between the Prestige LP and ACDF patients that was achieved at 24 months was maintained through seven years. However, there was a higher loss to follow-up in the two-level ACDF group, which may have biased results. Secondary outcome measures were similar between groups at 24-month follow-up. Data on adjacent-level surgeries were not collected prospectively, but assessed through AE documentation. At 24 months, surgery at the adjacent level(s) was 2.4% for the two-level Prestige LP group and 3.2% for the two-level ACDF group. Follow-up is continuing.

PRODISC-C

Murrey reported two-year results from the pivotal FDA randomized noninferiority trial to determine the safety and efficacy of ProDisc-C compared with ACDF.[11] In this trial, 103 patients received the ProDisc-C implant and 106 were treated with fusion; participants were blinded to intervention until following surgery. Follow-up between six weeks and two years was reported to be 85% in the summary of safety and effectiveness data presented to FDA.[11, 12] Reasons for the loss to follow-up were not described but appear to have included two patients in the ProDisc-C group who had the implant removed and five patients in the fusion group who had undergone additional surgical procedures to modify the original implant. Noninferiority was achieved for the FDA-defined combined end point of neurologic examination, NDI score, AEs, and device success, with 72% of ProDisc-C and 68% of fusion patients achieving success in all four component end points. Clinical outcomes at 24-month follow-up were reported to be similar in the ProDisc-C and fusion groups for the following: neurologic success (91% vs 88%), NDI score (21.4 points vs 20.5 points), reduction in pain scores (eg, 46-mm vs 43-mm reduction in neck pain on a visual analog scale [VAS]), and patient satisfaction (83 mm vs 80 mm), respectively.

Four-year interim follow-up of participants in this clinical trial were reported by Delamarter 2010.[13] All participants were followed in this FDA-regulated postapproval study. At 48 months, follow-up rates for ProDisc-C and ACDF were 63% and 46.2% respectively. It was not reported what proportion of these patients had not yet reached 48 months postsurgery or were lost to follow-up at that time point. Also included in this report was 24-month follow-up on 77% of 136 continued-access patients who received the ProDisc-C after the clinical trial. Clinical outcomes were similar across the three groups, with point estimates in favor of ProDisc-C. NDI score at 48 months was 20.3 for ProDisc-C and 21.2 for ACDF. Neurologic success was achieved in 88.9% of ProDisc-C patients compared with 74.4% of ACDF patients (p=0.067). There was a cumulative incidence of additional surgeries of 2.9% (3 patients) in the ProDisc-C group and 11.3% (12 patients) in the ACDF group. Two patients were converted to fusion with removal of

the device; 1 patient had decompression with supplemental fixation without removal of the device. At 48 months, five (7.7%) ProDisc-C patients had bridging bone.

Five-year results of this trial were published in 2013, with follow-up rates of 72.7% for ProDisc-C and 63.5% for ACDF.[14, 15] Outcomes on the NDI were similar (50%-60% improved), along with VAS score for arm pain (18 for both groups) and SF-36 scores. VAS score for neck pain was modestly improved with ProDisc-C (21/100) compared with ACDF (30/100), although the proportion of patients who achieved a clinically significant improvement in neck pain was not reported. Fewer patients with ProDisc-C (2.9%) than with ACDF (14.5%) had secondary surgery at either the index or adjacent level.

Seven-year follow-up on 72.7% (152/209) of patients was reported by Janssen in 2015.[16] Between two years and 7 years, there was no significant difference between ProDisc-C and ACDF patients for change in pain or function. Neurologic status was improved or maintained in a similar percentage of patients in both groups (ProDisc-C, 88%; ACDF, 89%). Secondary surgical procedures were significantly higher in the ACDF group (18%) than in the ProDisc-C group (7%; p=0.009), with an acceleration of secondary surgical procedures after five years in the ACDF group.

BRYAN CERVICAL DISC

Single-Level Bryan Cervical Disc

Two- and four-year results have been published from the IDE trial for the Bryan disc.[17, 18] The trial employed inclusion/exclusion criteria and a composite outcome identical to the ProDisc-C trial. A total of 582 patients were randomized to the Bryan disc (n=290) or ACDF (n=292). Thirty-seven patients declined surgery in the AIDA group; 80 patients declined surgery in the ACDF group. Twelve patients crossed over from AIDA to ACDF, one crossed over from ACDF to AIDA, and 2 patients were excluded from ACDF due to protocol violations, leaving 242 patients who underwent AIDA and 223 who underwent ACDF. In the AIDA and ACDF arms, mean age (44.4 years and 44.7 years), sex (45.5% and 51.1% men), and NDI scores (51.4 and 50.2), all respectively, were similar. All but one patient who underwent AIDA and three patients in the ACDF arm had documented neurologic abnormalities. After two-year follow-up, data were available for 230 (95%) patients from the AIDA group and 194 (87%) who underwent ACDF. The overall success outcome was achieved more often after AIDA (82.6% vs 72.7%), with a mean 4.1-point greater improvement in the NDI scores. As measured by the composite end point, AIDA was superior to ACDF. At 24 months, neck pain scores were lower following AIDA, while other secondary outcomes were similar. AE rates were similar in the two arms, with 1.7% in the AIDA and 3.2% in the ACDF arms requiring revision.

In 2011, four-year follow-up from the IDE trial was reported for 181 (75%) of 242 patients who received the Bryan disc and 138 (62%) of 223 patients who underwent ACDF.[17] It was reported that 25% of AIDA and 38% of ACDF patients failed to return for follow-up at 48 months, due in part to FDA and institutional review board approvals and the need for additional patient consent for the continuation study. Overall success was defined as an improvement of 15 or more points on the NDI, neurologic improvement, no serious AEs related to the implant or surgical implantation procedure, and no subsequent surgery or intervention that would be classified as a treatment failure. Four-year overall success rates were significantly higher in the Bryan (85.1%) than in the ACDF (72.5%) group. This finding was driven largely by differences in NDI success (90.6% of AIDA, 79.0% of ACDF). Neurologic success rates did not differ between groups. Arm pain was reduced from a baseline of 71.2 in both groups to 16.6 for the

Bryan disc and 22.4 for ACDF, the between-groups difference being statistically significant. Reduction in neck pain scores was also significantly better in the Bryan disc group (from 75.4 to 20.7) compared with the fusion group (from 74.8 to 30.6). Improvement in the SF-36 PCS score was also significantly greater in the AIDA group (15.8 vs 13.1). There was no significant difference in the percentage of additional surgical procedures at either the index (3.7% Bryan, 4.5% ACDF) or adjacent (4.1% Bryan, 4.1% ACDF) levels. FDA-required follow-up will continue for 10 years after the index surgery.

Authors' analysis of this trial noted that failure of other joint arthroplasty prostheses typically does not occur until at least 5 to 10 years postoperatively and that spinal arthroplasties also need serial assessments to determine whether complications (eg, wear-related failures, device fatigue, spinal instability) have developed. They concluded that, as with any motion-sparing device, "longer-term follow-up is necessary for assessment of potential problems related to bearing surface wear."

A post hoc subgroup analysis of 199 participants with myelopathy from the Prestige ST (n=111) and Bryan (n=88) trials found similar improvement in postoperative neurologic status and gait at 24 months (Prestige ST: AIDA, 90% [95% CI, 79% to 97%] vs ACDF, 81% [95% CI, 65% to 92%]; Bryan: AIDA, 90% [95% CI, 76% to 97%] and ACDF, 77% [95% CI, 76% to 97%]).[19] The authors noted that "although short-term results of cervical disc arthroplasty appear encouraging, studies with at least five to ten years of follow-up are required before cervical disc replacement can be viewed as a standard treatment for disc-based cervical myelopathy."

In 2010, Goffin reported four- and six-year follow-ups from phase one and two trials of the Bryan disc.[20] The total potential patient population for long-term follow-up was 98 patients (89 with one-level, nine with two-level); 59 patients were at least six years postoperative. Although four patients from the phase one study declined to participate in the extended follow-up study, their results were included in the safety data. Mean neck pain at four and six years postoperatively was 2.2 and 2.0, respectively. Mean arm pain at four and six years was 2.4 and 2.3, respectively. Six patients experienced events believed to be related to the device, including minor device migration, device removal, hoarseness, and vocal cord paralysis, while three of the six cases involved pain or neurologic symptoms. The prosthesis was removed from one patient at six years after the index surgery because of progressive spinal cord compression due to recurrent posterior osteophyte formation. About 90% of patients were classified as having excellent or good outcomes at four and six years. The success rate estimated by Kaplan-Meier analysis was 94% at seven years postsurgery.

Two-Level Bryan Cervical Disc

In 2009, Cheng reported two-year follow-up from an RCT comparing the Bryan disc to ACDF with autograft in 65 patients with two-level disc disease.[21] One patient from the arthroplasty group and two patients from the ACDF group were lost to follow-up. Neck pain and arm pain measured by VAS tended to be lower in the Bryan group (1.8 and 1.9, respectively) than in the ACDF group (2.5 and 2.4, respectively) at 12-month follow-up and continued to improve at two-year follow-up (Bryan, 1.5 and 1.4; ACDF, 2.6 and 2.7, respectively). NDI and SF-36 PCS scores were also significantly better in the Bryan group at both 12- and 24-month follow-ups. These results support the short-term safety of the Bryan disc in two-level disc disease; longer term results are needed to evaluate the safety and efficacy of this device versus ACDF for two-level disc disease.

KINEFLEX-C

In 2011, Coric reported the 24-month pivotal multicenter randomized IDE trial of the metal-on-metal Kineflex-C artificial disc (n=136) compared to ACDF performed with allograft and anterior plate (n=133).[22] There were no significant differences between the Kineflex-C and ACDF groups for operative time, blood loss, hospital length of stay, or reoperation rate at the index level. The overall success rate was significantly greater in the Kineflex-C group (85%) compared with the ACDF group (71%). (Overall success was defined as a composite measure of neurologic evaluation, >20% improvement in NDI score, no device failure, no reoperation at the index level, and no major device-related AE.) There were six (5%) index-level reoperations in the Kineflex-C group, including one case of metal sensitivity and two for device migration. There were seven (7.6%) index-level surgeries in the ACDF group, including three for pseudarthrosis and four for instrumentation failure (removal or revision of the original anterior plate and screw construct). There was no significant difference between groups in VAS pain or NDI scores. Although fewer Kineflex-C patients showed severe adjacent-level radiographic changes (9% vs 24.8%), the between-group difference was not significant for the adjacent-level reoperation rate (7.6% for the Kineflex-C group, 6.1% for the ACDF group) at short-term follow-up.

The need for longer term studies remains to assess device failure and other long-term complications. Given that no mechanical device has an infinite lifespan, the failure rate, timeframe, or consequences of failure of cervical arthroplasty devices needs to be studied.

MOBI-C

Single-Level Mobi-C

Mobi-C is the only artificial disc approved for one- or two-level cervical disc disease. The one-level Mobi-C trial randomized 169 patients to AIDA and 87 to ACDF.[23] Patient characteristics were generally similar to the other trials. Patient with multilevel disease or previously treated cervical disease were excluded from the trial. At 24-months, the follow-up rate was 93%. Designed as a noninferiority trial, noninferiority criteria were met for NDI mean improvement, percent NDI success (≥15-point improvement), and overall success. The overall protocol-specified success rate was higher in the Mobi-C group (73.7%) than the ACDF group (65.3%), which met noninferiority criteria but not superiority criteria. Cumulative subsequent surgical interventions at the index level were numerically lower in the AIDA group (1.2%) than the ACDF group (6.2%).

Hisey published two-, four- and five-year results from the single-level Mobi-C trial, with a follow-up rate of 85.5% for the Mobi-C group and 78.9% for ACDF at five-years.[24-26] The primary outcome was overall success, as defined by a modified FDA-approved measure designed for the postapproval study (PAS). The criteria for success were a minimum of a 30-point improvement in NDI score (100-point scale) compared to baseline; no device-related subsequent surgery; no device-related adverse events; no neurologic deterioration; and no intraoperative changes in treatment. Overall success in the Mobi-C group was noninferior to ACDF but did not achieve superiority, with a success rate of 61.9% for Mobi-C and 52.2% for ACDF. Range of motion was preserved with Mobi-C through 5 years, even though grade 4 HO was observed in 8.5% of Mobi-C patients. Adjacent segment degeneration was significantly lower with Mobi-C, but radiographically determined adjacent segment degeneration remained above 30% at five-year follow-up in this group. Throughout the five-year follow-up, Mobi-C patients had a lower incidence of subsequent surgeries (Mobi-C, 4.9%; ACDF, 17.3%; $p<0.01$).

Similar results were reported in an independently funded multicenter RCT from Asia of single-level arthroplasty with the Mobi-C device compared to ACDF (N=111).[27] Outcomes for pain and function were similar for the Mobi-C and ACDF groups at 48-month follow-up. There was significantly more radiographically determined adjacent-level degeneration and a higher incidence of secondary surgery with ACDF (one Mobi-C vs three ACDF patients).

Two-Level Mobi-C

Two- and four-year results from the two-level Mobi-C IDE trial were reported by Davis in 2013 and 2015, respectively.[28, 29] In this noninferiority trial, 225 patients received the Mobi-C device at two contiguous levels and 105 patients received two-level ACDF. At 24 months, the follow-up rate was 98.2% for the AIDA group and 94.3% for the ACDF group. At 48 months, the follow-up rate was 89.0% for AIDA and 81.2% for ACDF. Both groups showed significant improvement in NDI, VAS neck pain, and VAS arm pain scores from baseline to each follow-up point, with Mobi-C meeting the noninferiority margin. Subsequent testing for superiority showed that AIDA patients had significantly greater improvement than ACDF patients in NDI scores and had higher NDI success rates (79.3% vs 53.4% at 48 months, $p<0.000$) and overall success rates (66.0% vs 36.0% at 48 months) at all time points, respectively. AIDA resulted in significantly greater reduction in VAS neck pain at three and six months postoperatively but not at 12, 24, 36, or 48 months. Arm pain scores did not differ between the groups. The Mobi-C group had a lower reoperation rate (4.0% vs 15.2% $p<0.001$). At 48 months, adjacent-level degeneration was observed in 41.5% of AIDA patients and 85.9% of ACDF patients with available radiographs, while 25.6% of AIDA patients showed clinically relevant HO.

In 2016, Radcliff published five-year results from the Mobi-C 2-level IDE trial.[30] Follow-up rates were 82.7% of patients for the Mobi-C group (8.9% study failures) and 68.6% for the ACDF group (21.0% study failures). Excluding patients who dropped from the study due to death or device failures, follow-up rates were 90.7% for the Mobi-C group and 86.7% for the ACDF group. Improvement in the Mobi-C group was significantly better than in the ACDF group for the NDI and SF-12 PCS scores. There were no significant differences between groups for VAS neck and arm pain scores, neurologic status, or for SF-36 MCS scores. The FDA-defined composite measure of success was significantly better for the Mobi-C group (61%) than for the ACDF group (31%; $p<0.001$) and there were significantly fewer secondary surgeries in the Mobi-C group (7.1%) compared with the ACDF group (21%; $p<0.001$). This was due to fewer index-level reoperations (4.3% vs 16.2%, $p<0.001$) and adjacent-level reoperations (3.1% vs 11.4%) with the Mobi-C devices. Clinically relevant HO (grade III or IV) was observed in 29.7% of the Mobi-C patients, but the Mobi-C patients had significantly less adjacent-segment degeneration (50.7%) than ACDF patients (90.5%; $p<0.001$).

Post hoc analysis of data from the pivotal one- and two-level Mobi-C trials was reported by Bae in 2015.[31] Comparison showed no significant differences between one- and two-level AIDA on clinical outcomes (NDI, VAS, and SF-12 scores), major complication rates (4.3% for one-level AIDA, 4.0% for two-level AIDA), or subsequent surgery rates (3.0% of one-level, 4.0% of two-level). Clinically relevant HO was observed in 23.8% of one-level patients and 25.7% of two-level patients. Huppert compared outcomes between single- (n=175) and multilevel (2-4 levels, n=56) AIDA with the Mobi-C device in a prospective multicenter study from Europe.[32] The age of patients was significantly higher and the time since symptom onset was significantly longer in the multilevel group. At two years, there were no significant differences between groups for the radicular VAS, cervical VAS, and NDI scores. Range of motion was similar in the two groups. The overall success rate was 69% in both groups. There

was a trend for more patients in the single-level group to return to work (70% vs 46%) and for the return to work to occur sooner (4.8 months vs 7.5 months), respectively. A similar percentage of patients underwent adjacent-level surgery (2.3% for single-level, 3.6% for multilevel).

POROUS COATED MOTION CERVICAL DISC

Results of the two-year FDA-regulated multicenter randomized noninferiority trial of the porous coated motion (PCM) Cervical Disc were reported by Phillips in 2013.[33] Five- and seven-year follow-ups were reported by Phillips in 2015.[34] The investigator and surgical staff were not blinded to treatment assignment, and patients were informed of assignment after surgery. Of the 416 patients randomized (224 to PCM, 192 to ACDF), 340 (82% [189 to PCM, 151 to ACDF]) were per protocol for the 24-month primary end point of overall success. Overall success was defined as at least 20% improvement in NDI score; absence of reoperation, revision, or removal; maintenance or improvement in neurologic status; and absence of radiographic or major complications during the 24-month follow-up period. At 24 months, overall success was 75.1% in the PCM group and 64.9% in the ACDF group, which met both the noninferiority and superiority criteria. There was a trend toward a greater neurologic success rate in the PCM group (94.7%) compared with the ACDF group (89.5%, p=0.10). There was no significant difference between the groups for VAS pain scores, SF-36 scores, or implant- or surgery-related AEs (5.2% PCM vs 5.4% ACDF). Patients with prior fusion were included in this study. Overall success for prior fusion subgroups in this analysis was similar (65.4% PCM and 64.3% ACDF).

Follow-up at five years included 163 (74.8%) PCM and 130 (70.3%) ACDF patients.[34] At reporting, 68 (31.2%) PCM and 42 (22.7%) ACDF patients had reached seven years of follow-up. At five years, NDI success was modestly better in the PCM group (85.0%) than in the ACDF group (74.2%), and dysphagia was slightly lower (VAS score, 8.8/100 vs 16.9/100). Success on VAS pain scores did not differ significantly between groups for neck pain or worst arm pain, and there was no significant difference between groups for neurologic success rates. There was no significant difference between groups in subsequent secondary surgical interventions (PCM, 8.1%; ACDF, 12.0%). Radiographically determined adjacent-level degeneration was more frequent after ACDF (50.9%) compared with PCM (33.1%, p=0.006). Six percent of patients in the PCM group showed grade IV HO with bony ankylosis, while 94.4% of patients in the ACDF group showed fusion.

SECURE-C

The FDA-regulated SECURE-C trial was a multicenter nonblinded noninferiority trial with151 patients randomized to receive AIDA and 140 patients randomized to ACDF.[35, 36] An additional 89 nonrandomized patients were included in the published data.[36] Patients with multilevel disease or previously treated cervical disease were excluded from the trial. Overall success was defined by FDA as a 15-point or more improvement in NDI score; absence of reoperation, revision, or removal; stable or improved neurologic status, and absence of radiographic or major complications during the 24-month follow-up period. At 24 months, the follow-up rate was 87%. Noninferiority criteria (AIDA vs ACDF) were met for NDI mean improvement, rate of NDI success (89.2% vs 84.5%), neurologic success (96.0% vs 94.9%), and overall success (83.8% vs 73.2%), all respectively (posterior probability of 98.1% by Bayesian analysis) using FDA-defined criteria. The overall success rate, as specified in the protocol at 24 months (>25% improvement in NDI score, no removals, no complications) was

also higher in the SECURE-C group (90.1%) than in the ACDF group (71.1%), which met both noninferiority criteria, as well as superiority criteria (posterior probability of 100% by Bayesian analysis). Cumulative secondary surgical interventions at the treated level were lower in the AIDA group (2.5%) than the ACDF group (9.7%).

HYBRID SURGERY

Lu (2017) conducted a systematic review with meta-analysis to evaluate hybrid surgery (HS) compared to traditional discectomy and fusion (ACDF) for the treatment of multi-level cervical disc disease.[37] Hybrid surgery was defined as surgery containing elements of ACDF, artificial disc replacement, and anterior cervical corpectomy and fusion (ACCF) in varying proportions. A total of eight studies were meta-analyzed (169 patients undergoing HS and 193 ACDF). The average number of levels treated were approximately 2.5 for both groups. Overall, HS had a short return to work by 32 days and was associated with greater range of motion preservation (C2-C7) and less functional impairment compared to ACDF. There were no significant differences for post-operative pain, length of stay, or post-operative complaints.

REGISTRY DATA

Spine Tango

In 2016, Staub evaluated the clinical effectiveness of AIDA from 987 patients in the Spine Tango registry.[38] The primary outcome measures were neck and arm pain relief and the Core Outcome Measures Index (COMI). One analysis evaluated outcomes from a matched pair of patients (190 pairs) who met the selection criteria of published RCTs. With an average follow-up of 17 months, there were small but statistically significant differences in outcomes between AIDA and ACDF. The mean group differences on a 10-point scale for both pain measures were 0.6 points in postoperative neck pain ($p=0.04$) and 0.7 points in arm pain ($p=0.02$); mean COMI score difference was 0.8 points ($p=0.01$). Change scores did not differ significantly. The probability of being a responder (2-point change) was significantly better in the AIDA group for arm pain relief (78.4% vs 67.4%, $p=0.02$) and COMI score (81.6% vs 67.9%, $p<0.01$), but not neck pain relief (62.1% vs 57.9%, p=*NS*).

For patients excluded from the RCTs, most commonly due to age greater than 60 years or spondylosis, there were no significant differences in clinical outcomes between AIDA and ACDF. A third analysis compared outcomes of AIDA and ACDF in patients who had follow-up of more than two years (mean, 55.0 months; range, 27.0-76.5 months). After controlling for patient age, patients treated with AIDA had significantly higher responder rates for arm pain relief (80.0%) compared with patients treated with ACDF (64.9%; $p=0.05$), with no significant difference in responder rates between the two groups for neck pain relief or COMI. The rate of adjacent-level degeneration and secondary surgeries were not assessed.

ADVERSE EVENTS

Adjacent Segment Degeneration

A key question is whether cervical disc arthroplasty reduces adjacent segment degeneration, which is the hypothetical advantage of motion-preserving artificial discs. Five- and seven-year data from the pivotal trials described above suggest a reduction in both index-level and adjacent-level secondary surgeries with AIDA. However, other studies found no difference in adjacent-level degeneration between AIDA and ACDF.

In 2012, Jawahar published a report that included 170 patients (57 ACDF, 113 AIDA) with a median follow-up of 42 months (range, 28-54 months).[39] There was no significant difference in adjacent-level disease between ACDF (14%) patients and AIDA patients (17%). The mean period of freedom from adjacent-level disease was 46 months after ACDF and 49 months after total disc arthroplasty. Osteopenia and lumbar DDD significantly increased the risk of adjacent-level disease.

In 2010, Coric reported outcomes from 98 patients with one- or two-level cervical disc disease who had participated in one of three IDE studies (Bryan, Kineflex/C and Discover cervical disc).[40] Patients were evaluated with neurologic examinations, radiographs, and clinical outcome indices at 1, 3, 6, 12, 24, 36, 48, and 60 months. A minimum follow-up of 24 months (range, 24-67 months), data were available for 90 patients (53 arthroplasty, 41 ACDF). There were a similar number of reoperations, with four (7.5%) in the combined arthroplasty group (one at the adjacent level) and three (8.1%) in the ACDF group (all at the adjacent level). A 2013 report from this group reported minimum 48-month follow-up (range, 48-108 months) of 74 patients who had received a Bryan or Kineflex cervical disc.[41] There were three (7.3%) reoperations at the index (n=1) or adjacent levels (n=2) in the AIDA group and one (3%) adjacent-level reoperation in the ACDF group.

Device Failure

Reports of device failure may emerge with increased use of artificial discs and longer follow-up. One case report has described failure of a Bryan cervical disc due to a fatigue fracture of the flexible polyether urethane sheath at eight years after implantation.[42] Degradation of the sheath, including surface fissures and full-thickness cracks, has been observed in 27% of retrieved Bryan discs.[43] One case of anterior migration of the Mobi-C disc was reported.[44] Another case reported fragmented fracture of the ceramic-on-ceramic Discover® (Cervidisc Evolution) at one month after implantation.[45]

Dysphagia

A lower incidence of dysphagia has been reported with cervical arthroplasty in comparison with ACDF.[46] As part of the IDE trial for the PCM device, patients who underwent arthroplasty (n=151) or ACDF (n=100) self-reported dysphagia severity using the validated Bazaz Dysphagia Score. The arthroplasty group showed a significantly lower incidence of dysphagia at all time points (six weeks and 3, 6, 12, and 24 months after surgery). For example, at the six-week follow-up, moderate-to-severe dysphagia was reported in 18.7% of arthroplasty patients compared with 37.3% of ACDF patients, while at 12-month follow-up, moderate-to-severe dysphagia was reported in 4.3% of arthroplasty patients compared with 13.1% of ACDF patients.

Heterotopic Ossification

HO appears to be common with AIDA, but there is no evidence of a large impact on clinical outcomes. A meta-analysis of HO (McAfee grade 3-4) after AIDA was published by Chen in 2012.[47] Included in the meta-analysis were eight studies (total N=617 patients). The pooled prevalence of any HO was 44.6% at 12 months after AIDA and 58.2% at 24 months after AIDA. The pooled prevalence of advanced HO was 11.1% after 12 months and 16.7% after 24 months. Although no publication bias was identified, there was significant heterogeneity in study results.

The largest study included in the meta-analysis evaluated HO rates in 170 patients who had undergone cervical arthroplasty with one of three cervical discs (81 Bryan, 61 Mobi-C, 28 ProDisc-C) and had at least 12 months of follow-up.[48] HO was found in 40.6% of patients; the median time without HO was 27.1 months. HO occurred in 21% of Bryan patients, 52.5% of Mobi-C, and 71.4% of ProDisc-C patients. Tu assessed HO in a series of 36 patients (52 levels) who had received total disc replacement with the Bryan cervical disc and had completed clinical and radiologic evaluations.[49] HO was observed in computed tomography images in 50% of patients at a mean of 19 months of follow-up. However, only two (3.8%) treated levels showed a loss of segmental motion (<2°) by dynamic radiography. At a mean of 27 months of follow-up, clinical evaluation indicated a similar clinical success rates in patients who had and did not have HO (94.4% in both groups).

Progressive spinal cord compression due to osteophyte formation has been observed with cervical disc arthroplasty.[20]

Hypersensitivity Reaction

The first reported case of a delayed hypersensitivity reaction to metal ions after disc arthroplasty was in 2009.[50] Although no intracellular or extracellular metal alloy particles were detected in the tissue, the lymphocyte-dominated response was thought to be similar to reactions reported in patients with metal-on-metal hip prostheses. The patient had complete resolution of symptoms after implant removal and fusion. In 2011, Guyer reported four cases of a lymphocytic reaction to a metal-on-metal artificial disc (one Kineflex-C cervical disc and three lumbar) that required revision.[51] The mode of failure was compression of neural tissue or other adjacent structures by a soft tissue mass. Three patients had a good outcome after the explantation and revision surgery; one patient continued to have residual symptoms related to the neural compression caused by the mass. No hypersensitivity reactions have been reported from devices with a polyethene/polyurethane insert or from Prestige stainless steel implants, however, periprosthetic tissue explanted after one to seven years commonly showed focal metallosis.[43]

Subsidence

Extensive bone loss in the vertebral body and device subsidence has been reported as a complication in some patients four and six years after cervical arthroplasty.[52]

LUMBAR DISCS

Systematic Reviews and Technology Assessments

A 2007 TEC Assessment reviewed the evidence on artificial lumbar disc replacement devices.[53] No additional RCTs had been published since the FDA approval of the ProDisc-L in 2006. The Assessment found that both the Charité and ProDisc-L trials had been evaluated with one randomized clinical trial, designed as a noninferiority trial, with the comparator being fusion. The lower-than-expected success rates of fusion in the Charité and ProDisc-L trials raised questions regarding the validity of a noninferiority trial and the noninferiority margin selected. The Charité trial showed little evidence of superiority, and the ProDisc-L analysis was problematic because of missing values and uncertain outcomes for all patients. Given the invasiveness of the procedure, there were no obvious short-term advantages. In terms of the long-term goal of reducing stress on adjacent levels, the duration of follow-up was insufficient for evaluation. The authors concluded that neither of the noninferiority trials provided

convincing evidence of efficacy and the evidence for the ProDisc -L and Charité artificial disc is limited.

A 2013 update of this TEC assessment evaluated the five-year follow-up from the pivotal trial of the ProDisc-L.[54] The Assessment made the following conclusions:

- Additional study of the ProDisc-L in an appropriately powered clinical trial with minimum five-year follow-up is needed to confirm the results of the investigational device exemption (IDE) trial in patients with single-level chronic symptomatic DDD unresponsive to conservative management.
- Questions remain about the durability of the disc, in particular the long-term effects on patient health of polyethylene wear debris. Surgical revision of a failed or dysfunctional disc may be complicated and dangerous to the patient, so the lifespan of a prosthetic device is a key issue.
- The main claim of the artificial disc—that it maintains range of motion and thereby reduces the risk of adjacent-level segment degeneration better than fusion—remains subject to debate.

Khan (2026) published a systematic review of five observational and five RCTs including 2103 patients who underwent lumbar total disc replacement or interbody lumbar fusion.[55] Results indicated that LDR was associated with a 74% higher risk of removal rate compared to IBF (RR: 1.74, P = 0.0009), representing a statistically significant difference. Additionally, LDR demonstrated statistically significant improvement in range of motion compared to IBF (MD: 9.04, P < 0.00001). However, when comparing LDR and IDF groups, no statistically significant differences were observed across multiple outcome measures. These included operative time (MD: -12.91, p = 0.34), estimated blood loss (MD: 0.10, P = 1.00), adverse events (RR: 0.99, P = 0.97), reoperation rate (RR: 0.67, P = 0.63), Oswestry disability index success (MD: -8.13, P = 0.15), length of hospital stay (MD: -0.23, P = 0.14), reduction of back pain (MD: -8.13, P = 0.15), and overall success (RR = 1.14, P = 0.75).

Li published results from a meta-analysis comparing total disc replacement (TDR) and fusion surgery for patients with lumbar degenerative disc disease (DDD).[56] Seven studies were included in the analysis which included 1706 patients with DDD. Results show that TDR had better clinical outcomes including visual analog scale scores and Oswestry Disability Index scores. The authors also concluded that complications were significantly lower in the TDR group and that there were no differences in reoperation rates between groups. Due to significant heterogeneity in the data, authors were unable to determine differences in operative time, hospital stay, and blood loss. Studies included were low to moderate risk of bias, particularly due to the unblinded nature of the participants, personnel and outcome data that was addressed.

In 2017, Zigler reported results of a meta-analysis evaluating the safety and efficacy of lumbar total disc replacement (TDR) compared with fusion in patients with single-level degenerative disc disease at five years. The report was paid for by a manufacturer of a lumbar disc; four of the five authors disclosed receiving fees from one or more industry manufacturers. Four studies were included for analysis. The authors utilized the Cochrane Collaboration’s tool for assessing risk of bias, with majority of the bias categories being listed as unknown, i.e., overall quality was not thoroughly discussed. Pooled analysis found an increased improvement in the Oswestry disability index score, lower risk of reoperation, and slightly higher patient satisfaction towards TDR versus fusion. There was no difference in back pain score.

In 2017, Ding reported on a systematic review of five overlapping meta-analyses that compared total disc replacement (TDR) to fusion for DDD.[57] The primary studies for the meta-analyses were published between 2005 and 2011. The five meta-analyses arrived at different conclusions, but the highest quality review was determined to be a 2012 Cochrane review with an AMSTAR rating of nine. Cochrane reviewers concluded that, although there were statistically significant improvements in clinical outcomes of disability, pain relief, and quality of life with TDR for DDD in the short term, the differences were not clinically significant. In addition, prevention of adjacent segment and facet joint degeneration had not been adequately evaluated. Given the uncertainty of risks and benefits in the long-term, caution was advised. A limitation of the 2012 Cochrane review is that many of the selected studies used a Charité disc, which is no longer marketed in the United States.

A 2012 systematic review by Wang[58] reported on a pooled analysis of two randomized controlled trials[59, 60] that compared the risk of adjacent segment pathology (ASP) following lumbar artificial disc replacement with those following lumbar fusion. The overall strength of the evidence was graded as “moderate”, defined as moderate confidence that the evidence reflects the true effect, and further research may change the confidence in the estimate of effect and may change the estimate. The consensus statement was that this evidence demonstrated the risk of ASP requiring surgery is likely greater after fusion, but the risk is still quite rare. The strength of the statement was graded as weak due to the study limitations which included the lack of evaluation by an independent observer in both studies, and a high loss to follow-up in the Guyer study, increasing the risk of bias. Also, the confidence interval was relatively wide, which was attributed to the rarity of lumbar ASP and the limited number of ASP events. In addition, it is unclear whether different lumbar artificial discs can be generalized as essentially equal. The authors concluded that more studies are needed on this topic.

There are two older systematic reviews that concluded more research is needed.[61, 62]

The focus of the evidence summary below is on studies not included in the systematic reviews above.

INMOTION (formerly Charité)

The study for the Charité device consisted of an RCT comparing the artificial intervertebral disc to spinal fusion using a threaded fusion cage with autologous bone graft.[63] Patients were randomly assigned in a 2:1 fashion, with 205 receiving the artificial disc and 99 undergoing fusion. In this trial’s analysis of 267 patients followed for up to 24 months, the Charité artificial disc had a success rate of 63% compared with a success rate of 53% for BAK fusion, using a composite measure of outcomes that incorporated reduction of symptoms and absence of complications. The analysis showed noninferiority compared with BAK fusion using the composite measure of success but did not show statistically significant superiority in most outcome measures. The point estimate of 63% success did not show the artificial disc to be a highly successful treatment. In addition, the long-term effectiveness and health outcomes for artificial vertebral discs were uncertain.

In 2009, Guyer reported five-year follow-up of a subset of the patient cohort that participated in the IDE trial of the Charité artificial disc (previously described).[60] Of the initial 14 sites, six declined participation in the five-year continuation study, and an additional eight patients were excluded from analysis, leaving 233 patients from the original randomized trial. One hundred thirty-three cases were included in the five-year assessment (57% from the 8 sites). Based on

a denominator of 375 patients originally enrolled in the IDE trial, this report represented 30% of the study population. Given the limitations of the original RCT and the 50% to 70% loss to follow-up, results from the five-year follow-up cannot be interpreted.

Mean 17.3-year (range, 14.5-19.2 years) follow-up was reported for Charité types I-III intervertebral discs from the Charité hospital.[64] For the 53 (75%) of 71 patients available for clinical and radiologic examination, there were 16 type I discs (1984-1985), 25 type II discs (1985-1987), and 22 type III discs (1987-1989). Clinical evaluation at follow-up showed no significant difference between the three types of discs for Oswestry Disability Index (ODI) score, visual analog scale (VAS) score for pain, or overall outcome score. Of the 53 patients, 12 (23%) had a segmental fusion during follow-up due to implant failure or pain. Seven (58%) of the 12 were due to implant fractures and five underwent secondary operative instrumented fusion. Of the remaining 41 patients, 9 (17%) of 53 showed no signs of heterotopic ossification or ankylosis at follow-up, while 32 (60%) patients had ankylosis after 17 years. No signs of ASD were found in the nine (17%) cases without signs of ankylosis, fusion, or implant failure. Although no ASD was observed in the small percentage of implants that remained functional (17%), these patients were significantly less satisfied than those with spontaneous ankylosis based on ODI scores (52 vs 38) and VAS scores (6.1 vs 4.5). The authors, who had designed the prosthesis, concluded that this study demonstrated dissatisfying results after artificial disc replacement in most of the evaluated cases based on clinical and radiologic outcomes.

More studies are needed with larger sample sizes and longer term follow-up to answer questions regarding the potential for device failure, decay, wear, and facet degeneration.

Kineflex-L Versus Charité

The study for the Kineflex artificial disc was an RCT that compared the Kineflex-L to an artificial disc (Charité) already approved for sale.[65] There were 261 patients (204 randomized and 57 training cases) in the Kineflex group and 196 patients (190 randomized and six training cases) in the Charité group. The primary outcome measure was a composite success measure at 24 months of at least 15-point improvement in ODI score, no subsequent operative intervention related to the device, and no major adverse events. Twenty-four-month follow-up was obtained in 94.8% of the Kineflex-L group and 91.3% of the Charité group. There were no significant differences between the Kineflex-L and Charité groups for overall success (76.5% vs 74.7%, respectively) or in the individual components of success. Reoperations were performed in 10.3% of the Kineflex-L group and 8.4% of the Charité group. In the Kineflex group, the 11 reoperations were due primarily to lymphocytic reaction (n=2), device migration (n=2), and supplemental fixation implantations (n=5). In 2011, the authors of this study published a report of early failure of metal-on-metal disc prostheses in four patients due to a lymphocytic reaction, similar to that observed in metal-on-metal hip implants.[51]

Five-year follow-up was available for 66.0% of patients randomized to Kineflex-L and 70.9% of patients randomized to the Charité artificial disc.[66] Overall success rates were similar to those reported at two years. The percentage of patients undergoing subsequent surgery at the index level was 11.8% for the Kineflex-L group (including two devices removed due to lymphocytic reaction) and 11.6% for the Charité group. Interpretation of the five-year results is difficult due to high loss to follow-up.

ProDisc-L

The study for the ProDisc-L was an unblinded RCT that originally followed 242 patients for 24 months.[67, 68] Patients were randomized in a 2:1 ratio to ProDisc-L artificial disc replacement (n=161) or circumferential fusion (n=75). Using an FDA-requested composite outcome measure that incorporated symptom improvement and absence of complications, the ProDisc-L had a success rate of 53.4% and fusion had a success rate of 40.8%. This met prespecified criteria for a noninferiority margin of 10% and was statistically significant for a 1-sided statistical test of superiority (p=0.044). The calculations were based on between 88% and 91% of randomized patients—how or which patients were censored was not described. Two-year results from this trial were published in 2007, and 5-year follow-up was reported in 2012.[69-71] The 24-month report lacked detail on the number of patients lost to follow-up. The report also used alternative definitions of overall success, which resulted in a greater difference in rates of success between groups (experimental group, 63.5%; control group, 45.1%; p=0.005). Of the 236 patients randomized, 186 (79%; 134 ProDisc-L, 52 controls) were included in the five-year follow-up of clinical outcomes and 166 (70%; 123 ProDisc-L, 43 controls) were included for radiographic outcomes. Results showed noninferiority but not superiority of artificial disc replacement, with 53.7% of ProDisc-L patients and 50.0% of fusion patients achieving overall success at five years. This change in overall success in ProDisc-L patients between two year (63.5%) and five years (53.7%) indicates a possible decrement in response over time with the artificial disc. This decline in response rate was not observed in the standard fusion group and resulted in between-group convergence of the primary outcome measure over time. Post hoc analysis of radiographs found fewer patients with adjacent level degeneration in the ProDisc-L group (9.2%) than in the control group (28.6%). Adjacent level reoperations did not differ significantly between groups (1.9% ProDisc-L vs 4% controls). There were six (3.7%) ProDisc-L device failures.

Several individual components of the primary outcome measure were also statistically better in the ProDisc-L group compared to the fusion group at two years, but not at five years. For example, at five-year ODI scores improved by 15% or more in 78.6% of ProDisc-L patients compared with 76.5% of controls. A similar percentage of patients maintained or improved 36-Item Short-Form Health Survey (SF-36) Physical Component Summary scores compared with baseline (81.3% ProDisc-L vs 74.0% fusion), and overall neurologic success was achieved in 88.8% of ProDisc-L patients and 89.6% of fusion patients. Secondary surgeries at the index level occurred in 8% of ProDisc-L patients and 12% of fusion patients (p not reported). Device success, defined as absence of any reoperation to modify or remove implants and no need for supplemental fixation, was achieved in 96.3% of ProDisc-L patients and 97.3% of fusion patients. There was no significant difference in VAS scores between groups. For the ProDisc-L group, mean VAS scores improved from 75.9 at baseline to 37.1 at five years while for the same interval the fusion group they improved from 74.9 to 40.0. Analysis of VAS pain scores excluded patients who had secondary surgical interventions (11 ProDisc-L, 5 fusion). Narcotic use decreased in both groups, from a baseline of 84% to 44.6% in ProDisc-L patients and from a baseline of 76% to 42.5% in fusion patients.

The ProDisc-L for two-level lumbar DDD was reported in 2011 from a multicenter, randomized, FDA-regulated noninferiority trial.[72] All patients had DDD at two contiguous vertebral levels from L3 to S1 with or without leg pain, a minimum of six months of conservative therapy, and a minimum ODI score of 40. A total of 237 patients were treated in a 2:1 ratio with total disc arthroplasty or open circumferential arthrodesis (performed using both anterior and posterior open incisions). Postoperative evaluations were performed at six weeks and at 3, 6, 12, 18, and 24-months postoperatively. The total disc replacement group had faster surgeries (160.2 min vs 272.8 min), less estimated blood loss (398.1 mL vs 569.3 mL), and shorter hospital

lengths of stay (3.8 days vs 5.0 days). At 24 months, 58.8% patients in the ProDisc-L group and 47.8% patients in the arthrodesis group achieved the trial criteria for success, demonstrating noninferiority but not superiority of ProDisc-L. The ProDisc-L group showed significant benefit in percentage improvement in ODI scores (52.4% vs 40.9%), a greater percentage of patients who achieved at least a 15-point improvement in the ODI (73.2% vs 59.7%), greater improvement in the SF-36 Physical Component Summary scores (43.9 vs 39.2), and 6-month neurologic success (87.3% vs 71.6%), all respectively. A greater percentage of patients in the arthrodesis group required secondary surgical procedures (8.3% vs 2.4%). As noted in an accompanying commentary, there are a number of limitations to this study. Comparison with a procedure (open 360° fusion) that is not the criterion standard precludes decisions on the comparative efficacy of this procedure to the standard of care. Other limitations include the relatively short follow-up and lack of blinding of patients and providers.[73]

activL Versus ProDisc-L or Charité

Two-year outcomes from the multicenter IDE trial of the activL artificial intervertebral disc were reported by Garcia in 2015.[74] In this patient-blinded noninferiority trial, patients with DDD at L4-L5 or L5-S1 were randomized to treatment with activL (n=218) or an FDA-approved disc (n=106; ProDisc-L or Charité). Based on the primary composite end point (a ≥15 point improvement on ODI score, maintenance or improvement in neurologic status, maintenance or improvement in range of motion at the index level, freedom from additional surgery at the index level, freedom from serious device-related adverse events), activL was both noninferior ($p<0.001$) and superior ($p=0.02$) to the control group. Intention-to-treat analysis of secondary outcome measures showed similar improvements between activL and controls in back pain (74% vs 68%), ODI scores (75.2% vs 66.0%), device success (84.4% vs 84.9%), surgical reintervention (2.3% vs 1.9%), and patient satisfaction scores for the 2 groups (94.1% vs 93.1%), all respectively. Radiographic success, defined as maintenance or improvement in range of motion at the index level as measured by an independent core radiographic laboratory, was higher in the activL group than in the ProDisc-L and Charité controls (59% vs 43%, $p<0.01$).

Five-year results from the Garcia (2015) trial were reported by Yue in 2019.[75] Of 341 patients enrolled, 261 contributed data at five years (76.5%). The primary composite endpoint results demonstrated noninferiority at five years for activL versus control artificial discs. Freedom from serious adverse events through five years was 64% with activL and 47% with control artificial discs ($p<0.05$). This study was not powered to detect differences by different control devices and the control group includes patients who received a device that is no longer available in the United States. Additional limitations were a high loss to follow-up at five years, unblinded outcome assessment, and no blinding of patients at the five-year assessment. Furthermore, this study does not compare the activL discs to fusion or standard of care.

Maverick

Although the metal-on-metal Maverick disc is not marketed in the United States, 24-month results from an FDA-regulated multicenter IDE trial have been reported. [76] In this randomized nonblinded trial, 577 patients were allocated in a 2:1 ratio to the Maverick disc (n=405) or to anterior interbody fusion (control group) with INFUSE Bone Graft and tapered fusion cages (n=172)..All patients underwent a single-level, open anterior surgical procedure between the L4 and S1 level. The Maverick group had longer surgical times (1.8 hours vs 1.4 hours) and

greater blood loss (240.7 mL vs 95.2 mL). Hospitalization stays were similar for both groups (2.2 days vs 2.3 days). At 24 months, radiographic fusion was observed in 100% of the control patients. Heterotopic ossification was observed in 2.6% of patients with the artificial disc.

The FDA-defined measure of overall success was a combination of ODI scores, neurologic status, disc height, no additional surgery classified as failure, and no serious device or device/surgical procedure-related adverse events at the 24-month follow-up. Patients who received the Maverick artificial disc had superior outcomes to fusion for overall success (73.5% vs 55.3%) and in the component scores, all of which showed improvement (ODI scores, 82.2% vs 74.6%; back pain, 53.4 points vs 49 points; SF-36 Physical Component Summary scores, 17.0 vs 14.3). Although leg pain scores did not differ between groups, global perceived effect ("completely recovered" or "much improved") was higher in the Maverick group (78.1% vs 67.4%). The Maverick group also had fewer implant or surgical procedure-related adverse events (1% vs 7%), though two implants in the Maverick group were removed, one considered related to an allergic reaction. While return-to-work intervals were shorter, favoring the Maverick group (median, 75 days vs 96 days), the percentage of patients in both groups working at 24 months was similar (74.1% vs 73.4%). Follow-up beyond 24 months with this two-piece, metal-on-metal implant is needed, particularly in light of emerging complications (eg, pseudotumor formation) with other metal-on-metal implants (see evidence review 7.01.80).

FlexiCore

Preliminary results on the FlexiCore metal-on-metal intervertebral disc were presented in 2008 from two of the sites involved in the investigational device trial.[77] Results were reported for 76 patients enrolled at the two sites (of the entire study cohort of 401 patients) who had been randomly assigned with a ratio of 2:1 to FlexiCore or fusion (control); nine subjects did not receive the index surgery, 44 patients were treated with the artificial disc, and 23 patients were treated with fusion. Compared with fusion, placement of the artificial disc was associated with better initial outcomes: less blood loss (97 mL vs 179 mL), reduced operating time (82 min vs 179 min), and reduced hospital lengths of stay (two days vs three days). ODI and VAS pain scores did not differ significantly between groups. At 24 months, the ODI scores had improved, decreasing from 62 to 6 in the FlexiCore group and from 58 to 12 in the fusion group. Likewise, VAS scores had improved, decreasing from 86 to 16 in the FlexiCore group and from 82 to 20 in the fusion group. Eight patients in each group required interventional surgery.

Other Artificial Discs

In 2009, Berg published two-year follow-up of an RCT of one- and two-level total disc replacement.[59] Five-year follow-up of patients in this study was reported in 2013.[78] Patients (n=152) with symptomatic DDD in one or two motion segments between L3 and S1, with lower back pain as a predominant symptom, were randomly assigned to 1 of 3 total disc replacement devices available in Sweden (Charité, ProDisc, or Maverick, n=80) or to instrumented fusion (posterolateral or posterior lumbar interbody fusion, n=72). Randomization was stratified for number of levels, with 56% of total disc replacement patients having one-level surgery compared with 46% of fusion patients. Only patients without a preference for type of treatment were enrolled in the trial; they were informed about randomized allocation on arrival at the hospital for surgery. No patient left the study when informed of assignment. There was 100% follow-up at the one- and two-year assessments and 99.3% at the five-year assessment. The primary outcome, which does not appear to be a validated measure, was a global assessment

of back pain (“total relief,” “much better,” “better,” “unchanged,” or “worse”). The percentage of patients in the disc replacement group who reported being pain-free was 30% at the one- and two-year follow-ups, and 38% at 5-year follow-up. The fusion group reported poorer outcomes: 10% reported being pain-free at one-year and 15% reported being pain-free at two- and five-years. The total disc replacement group had lower mean VAS scores for pain at one- and two-years (25.4 vs 29.2, respectively) and better outcome scores on a quality-of-life scale and the ODI at one year (19.5 vs 24.9, respectively), but not the two-year follow-up (20.0 vs 23.0, respectively). At five years, the disc replacement group had modestly improved outcome scores for VAS back pain (23 vs 31) and ODI (17 vs 23) scores. The most common reason for additional surgeries in the disc replacement group was fusion of the index level believed to cause persistent or recurrent pain (5%). The most common reason in the fusion group was surgery at an adjacent level (7%). Twenty-two disc replacement patients underwent postoperative facet block due to remaining pain. Twenty fusion patients had their instrumentation removed due to persistent or recurrent pain. The investigators found no association between achievement of surgical goals (absence of mobility with fusion, maintenance of mobility with disc replacement) and clinical outcomes at two years.[79]

Hybrid Procedures

In 2015, Hoff published an RCT with 62 patients that compared a hybrid procedure (anterior lumbar interbody fusion at one level and a Maverick disc at another level) to two-level circumferential fusion.[80] VAS score for pain was significantly lower by about one point on a 10-cm scale in the hybrid group compared to the two-level fusion group both postoperatively and at three-year follow-up. There was no significant difference between groups in ODI scores. ASD did not differ significantly between groups.

Longer Term Follow-up

Putzier (2025) published a study on the comparison of lumbar interbody fusion and total disc arthroplasty with a mean follow-up of 14 years.[81] A total of 120 patients were included, with 60 patients assigned to each group. During the follow-up period, 28 patients were lost to follow-up, and an additional three patients were excluded due to revision surgery. Among the remaining patients, both groups demonstrated significant improvements in Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) scores over time (all $p < 0.001$). Although clinical scores showed a slight decline by the final follow-up assessment, they remained significantly better than preoperative baseline levels. When comparing the two treatment groups overall, no significant differences were found between ALIF and TDA. However, a more detailed subgroup analysis revealed important distinctions based on the surgical level. Specifically, ALIF demonstrated superior outcomes compared to TDA when performed at the L5/S1 level (ODI posthoc test at final follow-up $p = 0.005$), while outcomes between the two procedures were comparable when performed at the L4/5 level.

Siepe (2014) reported minimum five-year follow-up for 181 patients implanted with the ProDisc II at their institution.[82] This represented 90.0% of the initial cohort of 201 patients from this prospective clinic-funded quality review. Disc replacement was performed to treat predominantly axial low back pain (≥80%). Radiculopathy was a contraindication, and all patients underwent fluoroscopically guided infiltrations of the facet and sacroiliac joints to rule out non–discogenic pain sources. Baseline ODI and VAS pain scores, assessed by investigators not involved in pre- or postoperative decision making, were 42 and seven, respectively. After a mean of 7.4 years (range, 5.0-10.8 years), VAS pain scores remained

significantly improved over baseline (mean, 3.3; p<0.000), although a slight increase (more pain) in score (0.66 on a 10-point scale) was observed between 48 and 120 months (p<0.05). ODI scores remained stable throughout follow-up, with a final score of 22 (p<0.001). The complication rate for single-level disc replacement was 11.9% compared with 27.6% for bisegmental disc replacement (p=0.031). Overall satisfaction rates were 89.1% for single-level and 69.0% for two-level disc replacement.

Five-year results of lumbar disc arthroplasty from the Swiss Spine Registry were published in 2014.[83] Five devices were used during the period of study (ActivL, Charité, Dynardi, Maverick, ProDisc-L). Of 248 patients eligible for the five-year study, follow-up was obtained from 77% at one year, 44% at two years, and 51.2% at five years. In the 127 patients followed through five years, there was a significant reduction of VAS scores for back pain (73 to 29) and leg pain (55 to 22). The presence of radiculopathy did not appear to have been an exclusion for disc arthroplasty at these institutions. The overall complication rate at five years was 23.4%, which included a new radiculopathy in 10.5% of patients; the rate of adjacent segment degeneration was 10.7%, and 43.9% of patients had osteophytes that might potentially affect range of motion. The cumulative probability of device survivorship at five years was calculated to be 90.4%. Another case series identified followed 55 patients for an average of 8.7 years after disc replacement with the ProDisc-L; 60% of patients reported excellent results.[84] Additional studies have reported on the implantation of artificial discs at two levels in the lumbar spine.[85]

In 2015, Lu reported minimum 11-year follow-up on 32 of 35 patients implanted with the Charité III.[86] Of the three patients not included in this prospective study, one chose not to participate, one was lost to follow-up, and one died of unrelated causes. Prior to surgery, VAS score for back pain was 8.5 and ODI score was 41.4; the mean duration of symptoms was 5.4 years. At an average of 11.8 years after device implantation (range, 11.3-13.8 years), VAS score improved to 1.5 (p=0.0015), ODI score improved to 13.2 (p=0.0047), and 87.5% had a successful outcome based on FDA criteria. There were no device failures or major complications (one patient developed severe leg pain associated with adjacent segment degeneration and had spinal decompression). Heterotopic ossification was observed in 71.4% of segments, but was associated with a decrease in range of motion in only 25.7% of segments. The authors proposed several reasons for the high success rate in this group, including strict selection criteria and the lighter body weight of most Chinese compared to Western patients (e.g., less load on the prosthesis).

Adverse Events

Complications with artificial lumbar discs are emerging with longer term follow-up. One study from Asia reported that clinical outcomes with both the Charité and the ProDisc were fairly good, but the facet joint of the index level and the disc at the adjacent level showed aggravation of the degenerative process in a significant number of patients, regardless of the device used.[87] Another study reported that progression of facet degeneration (29% of levels replaced with the ProDisc II) was associated with female sex, malposition of the prosthesis on the frontal plane, and 2-level total disc replacement.[88] Analysis of postoperative pain patterns in 58 (33%) patients of 175 implanted with the ProDisc II showed facet joint pain in 22 (13%) and sacroiliac joint pain in 21 (12%).[89] Another report described late complications in 75 patients who had received an earlier generation SB Charité prosthesis.[90] Because all patients had been originally treated by other surgeons, the percentage of implant failure cannot be determined from this report. Nonetheless, the mean interval between insertion and retrieval of the prosthesis nine years (range, 3-16 years). The most frequent complications included

subsidence (n=39), disc prosthesis too small (n=24), adjacent disc degeneration (n=36), degenerative scoliosis (n=11), facet joint degeneration (n=25), and metal wire breakage (n=10). The report indicated that good placement and good sizing of the disc prosthesis appeared problematic for many patients, adjacent-disc degeneration was seen in many patients, and polyethylene wear with inflammatory fibrous tissue containing wear debris was observed. The report suggested that wear mechanisms of artificial discs may be similar to artificial hips and knees and that, due to nearby vasculature and scar tissue from the original surgery, disc retrieval could be difficult and dangerous. These durability issues suggest that long-term health outcomes after disc implantation in young active patients may become a clinically significant issue.

In 2011, Guyer reported four cases of a lymphocytic reaction to a metal-on-metal artificial disc (one Kineflex-C cervical disc, two Kineflex-L lumbar discs, one Maverick lumbar disc) that required revision.[51] The mode of failure was compression of neural tissue or other adjacent structures by a soft-tissue mass. Three patients had a good outcome after the explantation and revision surgery; one patient continued to have residual symptoms related to the neural compression caused by the mass. Two other cases of a granulomatous mass (pseudotumor) with the metal-on-metal Maverick prosthesis have been reported.[91, 92] One caused iliac vein occlusion and spinal stenosis; the second resulted in spinal compression and paraplegia.

Section Summary

The evidence for the lumbar artificial intervertebral disc in individuals who have lumbar degenerative disc disease includes randomized controlled trials (RCTs) with five-year outcomes and case series with longer term outcomes. The Charité disc has been withdrawn from the U.S. market, and its successor, the INMOTION, is not marketed in the United States. Five-year outcomes for the ProDisc-L RCT have provided evidence for the noninferiority of artificial disc replacement. Superiority of ProDisc-L with circumferential fusion was achieved at two but not five years in this unblinded trial.

PRACTICE GUIDELINE SUMMARY

CERVICAL DISCS

North American Spine Society

The 2015 North American Spine Society (NASS) guidelines state that “Cervical artificial disc replacement (CADR, also known as cervical total disc replacement and cervical arthroplasty) may be indicated for the following diagnoses with qualifying criteria, when appropriate:

1. Radiculopathy related to nerve root compression from one or two-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
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from one or two-level degenerative disc disease from C3-4 to C6-7 with or without neck pain.”

LUMBAR DISCS

North American Spine Society

The North American Spine Society (NASS) published a 2019 coverage policy recommendation that considered lumbar artificial disc replacement to be indicated as an alternative to lumbar

fusion for patients with discogenic low back pain who meet all of the following criteria from the NASS Lumbar Fusion Recommendation[93]:

- Symptomatic single level lumbar disc disease at L3-L4, L4-L5 or L5-S1 level
- Presence of symptoms for at least six 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

American Pain Society

In 2009, the American Pain Society's (APS) practice guidelines concluded there was "insufficient evidence" to adequately evaluate long-term benefits and harms of vertebral disc replacement.[94] The guideline was based on a systematic review of the evidence.[95] The rationale for the recommendation was that, although artificial disc replacement has been associated with similar outcomes compared with fusion, the trial results were only applicable to a narrowly defined subset of patients with single-level degenerative disease, and the type of fusion surgery in the trials is no longer widely used due to frequent poor outcomes.

SUMMARY

The current research for single level or simultaneous two contiguous level cervical disc replacement using an artificial intervertebral disc shows an improvement in health outcomes for the cervical spine. Therefore, the use of single level and simultaneous or subsequent second-level placement of an artificial intervertebral disc in cervical spinal levels between C3 and C7 is considered medically necessary when policy criteria are met and not medically necessary when policy criteria are not met.

The current research for single level lumbar disc replacement using an artificial intervertebral disc shows an improvement in health outcomes for the lumbar spine in certain populations. Therefore, the use of single level placement of an artificial intervertebral disc in lumbar spinal levels between L4 and S1 is considered medically necessary when policy criteria are met and not medically necessary when policy criteria are not met.

Current research does not show an improvement in health outcomes and therefore, all other uses of artificial intervertebral discs are considered investigational, including but not limited to placement at spinal levels other than cervical segments between C3 and C7 and artificial intervertebral cervical disc placement at more than two spinal levels.

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CODES

Codes	Number	Description
CPT	22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy 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 osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)
	22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (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	;lumbar
	22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical

Codes	Number	Description
	22865	Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace
	22899	Unlisted procedure, spine
	0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
	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)
	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)
	0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment
HCPCS	None	

Date of Origin: *October 2003*