MEDICAL POLICY

ARTIFICIAL DISC REPLACEMENT

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By: Roger Hinkson, MD, MPH
Consulting Medical Director

POLICY

- The use of the artificial disc is still considered experimental for both the lumbar and cervical regions.
- Although cervical artificial disc replacement holds promise, there are insufficient studies establishing long-term safety and efficacy.
- There is insufficient long-term evidence to draw conclusions comparing artificial disc replacement with other recommended treatment options, including fusion.
- Most studies cover less than five years, giving an incomplete assessment of adjacent disc disease, device durability, revisability, and complications. This is inadequate in light of pathology with a long-natural history.
- Although currently FDA approved, the disc prosthesis is generally not covered by non-workers compensation health plans.

SUPPORTING DOCUMENTATION

ODG- Low Back Chapter
Not recommended. While artificial disc replacement (ADR) as a strategy for treating degenerative disc disease has gained substantial attention, it is not possible to draw any positive conclusions concerning its effect on improving patient outcomes. The studies quoted below have failed to demonstrate superiority of disc replacement over lumbar fusion, which is also not a recommended treatment in ODG for degenerative disc disease. The anatomic implications of total disc replacement are different from total hip or total knee replacements, and the perceived corollary between total disc replacement and total hip or knee replacement is not justified. Furthermore, longevity of this new procedure is unknown, especially with a relatively young average age in workers’ comp patients, and the consequences of failure of an implant in close proximity to caudal equina and vital organs (e.g., aorta, vena cava and iliac arteries) are of
concern. Plus, adjacent segment disease seems to be a natural aging process, and despite early intentions, ADR has not proven any benefit in altering that progression compared to fusion. See separate document with all studies focusing on Disc prosthesis. (Cinotti-Spine, 1996) (Klara-Spine, 2002) (Zeegers, 1999) (Blumenthal, 2003) (Zigler, 2003) (McAfee, 2003) (Anderson-Spine, 2004) (Gamradt-Spine, 2005) (Gibson-Cochrane, 2005) See also the Neck Chapter. Total disc replacements should be considered experimental procedures and should only be used in strict clinical trials. (deKleuver, 2003) At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement. (McAfee-Spine, 2004) Even though medical device manufacturers expect this to be a very large market (Viscogliosi, 2005), the role of total disc replacement in the lumbar spine remains unclear and predictions that total disc replacement (TDR) will replace fusion are premature. One recent study indicates that only a small percentage (5%) of the patients currently indicated for lumbar surgery has no contraindications to TDR. (Huang-Spine, 2004) Because of significantly varying outcomes, indications for disc replacement need to be defined precisely. In this study better functional outcome was obtained in younger patients under 40 years of age and patients with degenerative disc disease in association with disc herniation. Multilevel disc replacement had significantly higher complication rate and inferior outcome. (Siepe, 2006) On the other hand, this case series reporting on the long-term results of one-level lumbar arthroplasty reported that after a minimum 10-year follow-up, 90% of patients had returned to work, including 78% of patients with hard labor level employment returning to the same level of work. (David, 2007) According to this prospective, randomized, multicenter FDA IDE study, the ProDisc-L has been shown to be superior to circumferential fusion by multiple clinical criteria. (Zigler, 2007)

Recent research: A high quality meta-analysis/health technology assessment concluded that there is insufficient evidence to draw extensive efficacy/effectiveness conclusions comparing artificial disc replacement (ADR) with a broad range of recommended treatment options, including conservative nonoperative care, since, other than spinal fusion, there are currently no direct comparison studies. With respect to the comparison of lumbar artificial disc replacement (L-ADR) and fusion, overall clinical success was achieved in 56% of patients receiving L-ADR and 48% receiving lumbar fusion. Though the results suggest that 24-month outcomes for L-ADR are similar to lumbar fusion, it should be noted that for the lumbar spine, the efficacy of the comparator treatment, lumbar fusion, for degenerative disc disease remains uncertain, especially when it is compared with nonoperative care. Given what is known about lumbar fusion as a comparator and having evidence that only compares L-ADR with lumbar fusion limits the ability to fully answer the efficacy/effectiveness question. (Zigler, 2007) (Blumenthal, 2005) (Dettori, 2008) Although there is fair evidence that artificial disc replacement is similarly effective compared to fusion for single level degenerative disc disease, insufficient evidence exists to judge long-term benefits or harms. (Chou, 2009) The ECRI health technology assessment concluded that the safety data on lumbar ADR are inadequate to draw conclusions about long-term safety. (ECRIa, 2009) This RCT compared disc prosthesis with multidisciplinary rehabilitation for 12-15 days, and found differences in favor of surgery, but the difference between groups was smaller than the difference that the study was designed to detect. In concluding, given the association of surgery with potentially serious complications, and the considerable improvement in the rehabilitation group, they recommended considering a multidisciplinary rehabilitation first. (Hellum, 2011) A just-released Cochrane systematic review concludes that the lumbar artificial disc is still not ready for routine clinical use because the long-term risks and benefits of this treatment have not been documented adequately. (Jacobs, 2012) A
Back Letter article entitled, "Future Still Uncertain for the Lumbar Artificial Disc," reports that patients, physicians, and healthcare systems were wise to resist the massive wave of publicity in favor of the artificial disc for the treatment of chronic back pain. (Wiesel, 2012)

**Safety & Complications:** There is moderate evidence that L-ADR is as safe as lumbar anterior or circumferential fusion. The studies primarily reflect outcomes measured up to 24 months and therefore questions remain regarding the long-term safety and efficacy of L-ADR compared with fusion. This is an important matter, particularly in workers’ comp patients who may be younger. Since these are mechanical devices, future failure is a possibility and may influence complication rates and costs in the longer-term. (Dettori, 2008) Revision procedures have included posterior stabilization or anterior revision or conversion to arthrodesis. Risk of great vessel and retroperitoneal injury is greater than with primary procedures. (Patel, 2008) We do not know the long-term failure rate or impact of particular wear on these devices, and the theoretical position that symptomatic adjacent segment disease leads to more surgery after fusion compared to less aggressive treatment is poorly founded, plus these devices appear at best to yield results equal to or only incrementally better than fusion for the same indications. (Resnick, 2007)

**Indications:** Indications for L-ADR include, among other factors, primary back pain and/or leg pain in the absence of nerve root compression with single level disease. This group of patients is different than those undergoing cervical ADR and results from one group should not be inferred to the other. Cervical ADR is performed in patients with radiculopathy (cervical nerve root compression) causing arm pain and possibly motor weakness, or even myelopathy (compression of the spinal cord that could affect upper extremities, lower extremities, bowel, and bladder function). The problem of identifying those likely to respond to treatment is of concern for L-ADR in that the surgical procedure is designed to treat degenerative disc disease that is thought to be the origin of the patient’s pain, but certainty around the diagnosis as the cause of low back symptoms varies. Though L-ADR for degenerative disc disease has been compared with lumbar fusion, not all patients who get a fusion are candidates for L-ADR, including patients with nerve root compression, spondylolisthesis, stenosis, facet mediated pain and osteoporosis. In fact, the proportion of patients who have an indication for L-ADR make up only about 5% of those who might undergo lumbar fusion. (Dettori, 2008)

**ODG- Neck Chapter**

Under study, with recent promising results in the cervical spine, but not recommended in the lumbar spine. While comparative studies with anterior cervical fusion yield similar results, the expectation of a decrease in adjacent segment disease development in long-term studies remains in question. And there is an additional problem with the long-term implications of development of heterotopic ossification. Additional studies are required to allow for a “recommended” status. These should include an evaluation of the subset of patient who will most benefit from this procedure as well as study of advantages/disadvantages of disc design and surgical procedure in terms of outcomes (particularly for development of heterotopic ossification and adjacent segment disease). This recommendation is based on balancing what we know so far about the benefits and the risks for the patient. Adjacent segment disease seems to be a natural aging process, and ADR has not proven any benefit in altering that progression. The risks of heterotopic calcification associated with ADR may make it a sure way to end up with a solid fusion, and major risks also include potential revisions and technical learning curve issues with widespread use.
Overall Comparison to Fusion: Overall studies have demonstrated statistically significant non-inferiority of ADR vs. fusion with superior trending on many outcomes but limited evidence of statistical superiority. This has persisted for longer-term follow-up (three to five years). Long-term studies have shown that necessity of adjacent-level surgery is similar in both the fusion and ADR groups along with similar rates of development of adjacent-segment disease. Complication rates are similar. Study quality is often severely limited with high dropout rates and there is no comparison to a non-surgical treatment. Neither treatment has been found to produce complete disappearance of symptoms. Return to work appears earlier in the ADR group but overall employment rate is not different at 2 years (including for a workers’ compensation cohort) and 5 years. (Zechmeister, 2011) (Steinmetz, 2008) (Jawahar, 2010) (Kim, 2009) (Garrido, 2010) (Fekete, 2010) (Dettori, 2008) (Pointillart, 2001) (Cinotti, 1996) (Klara, 2002) (Zeegers, 1999) (Sekhon, 2003) (Sekhon, 2004) (Porchet, 2004) (Pimenta, 2004) (Sasso, 2007) (Heller, 2009) (Mummaneni, 2007) (Murrey, 2009) (Burkus, 2010) (ECRiB, 2009) (Tumialán, 2010) (Delamarter, 2010) (Kelly, 2011) See also the complete list, discussion, and rating of other Disc prosthesis references in the Fusion References Chapter.

Recommended Indications: The general indications for currently approved cervical-ADR devices (based on protocols of randomized-controlled trials) are for patients with intractable symptomatic single-level cervical DDD who have failed at least six weeks of non-operative treatment and present with arm pain and functional/neurological deficit. At least one of the following conditions should be confirmed by imaging (CT, MRI, X-ray): (1) herniated nucleus pulposus; (2) spondylosis (defined by the presence of osteophytes); & (3) loss of disc height. (Dettori, 2008) At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement, whereas cervical radiculopathy is an inclusion criteria for the FDA investigations of cervical arthroplasties. (McAfee, 2004) Decompression of nerve roots and/or the spinal canal is often the primary intervention that necessitates disc replacement with a goal of restoration of intervertebral disc and foraminal height to prevent recurrence of nerve root compression. Implant of a total disc requires intact ligaments, integrity of the facet joints, vertebral bodies with intact endplates and good bone quality. (Fekete, 2010) (Cepoiu-Martin, 2011)

Myelopathy: ADR is also recommended for myelopathy. The findings from two cohorts at two years postoperatively suggest that arthroplasty is equivalent to arthrodesis for the treatment of cervical myelopathy for a single-level abnormality localized to the disc space, but the study did not evaluate the treatment of retrovertebral compression as occurs in association with ossification of the posterior longitudinal ligament. (Riew, 2008)

Recommended exclusions: Suggested exclusions include evidence of facet arthritis, spinal instability or significant deformity. While patients with myelopathy are suggested as candidates this is precluded if there is evidence of multilevel pathology or significant degeneration. Other suggested exclusions include the following: (1) axial neck pain as the solitary presenting symptom; (2) osteoporosis/osteopenia; (3) spinal stenosis by hypertrophic spondyloarthrosis; (4) severe spondylosis (defined as bridging osteophytes, a loss of disc height greater than 50%, or absence of motion at less than 2%); (5) active infection; (6) material allergies; (7) presence of underlying comorbid disease such as HIV, hepatitis B or C, insulin-dependent diabetes, and/or autoimmune spondyloarthropathies such as rheumatoid arthritis; & (8) morbid obesity (BMI > 40). As of yet there are no recommendations for precautions in terms of underlying psychiatric pathology, smoking history, current drug use history, workers’ compensation status, or litigation status. (Auerbach, 2008) (Zechmeister, 2011) (Sasso, 2007)
Rationale for development of this treatment: It is generally suggested that mobility in a degenerate joint is the cause of pain. In the spine a problem arises as the mechanism of pain is incompletely understood. Proponents of artificial disc replacement point out that while there is evidence of a high success rate for anterior cervical discectomy and fusion (ACDF) for treatment of radiculopathy and myelopathy, the procedure is thought to increase biomechanical stresses at adjacent segments that may hasten degeneration. This concept is controversial as there is debate over whether this is a stand-alone phenomenon accompanying fusion or a part of natural history of degeneration. By maintaining adjacent level kinematics the rate of adjacent level degeneration is thought to lessen, although there is limited evidence to support this. Other proposed benefits include quicker return to normal employment and lifestyle and elimination of risks and morbidity with bone graft procurement. Pseudoarthrosis is also not a problem with disc replacement. (Phillips, 2005) (Auerbach, 2008) (Cepoiu-Martin, 2011) (Zechmeister, 2011)

Concerns with use: There is an increasing interest in spinal arthroplasty as an alternative to fusion in conjunction with cervical discectomy, but at this time there are no comparative studies of ADR with other treatment modalities besides fusion. Longevity of this new procedure is unknown, which is important based on the targeted age of most patients who fit the current criteria for treatment (with a relatively young average age in workers’ compensation patients). There is limited data in terms of mechanical failure and aseptic loosening. There is also limited evidence as to the long-term effect on index-level facet arthrosis and/or adjacent level degeneration/disease. It has been noted that the theoretical position that symptomatic adjacent segment disease leads to more surgery after fusion compared to less aggressive treatment is poorly founded, plus theses devices appear at best to yield results equal to or only incrementally better than fusion for the same indications. (Resnick, 2007) Finally, the consequences of failure of an implant in close proximity to the spinal cord, the esophagus, and the trachea are of concern. Current literature suggests that an analysis of these types of questions will take from five to ten years.

Complications: Implant malposition, loosening, subsidence, implant migration, fractures and infection have all been reported and may necessitate retrieval and proceeding with an interbody fusion. Other reported complications include delayed fusion around the prosthesis, asymmetric endplate preparation resulting in postoperative kyphosis, and reduction in vertebral body height. The most common complications of both ADR and fusion are wound infections, dysphagia/dysphonia and allergic reactions. (Zechmeister, 2011) (Anderson, 2008) (Yi, 2010)

Adjacent segment degeneration and disease: Early studies of the Bryan disc vs. ACDF patients found non-significant difference in adjacent level surgery. The incidence of new symptomatic adjacent-disc disease in the TDR group was 1.3% vs. 13.9% in the ACDF group. A conclusion was that moderate or severe kyphosis was probably a contraindication for TDR as it produced significant decrease in subsequent motion and kyphosis might persist. (Robertson, 2005) While a 4-year study showed a 5% reoperation rate for adjacent level disease in the ADR group vs. 12% for the fusion group (not statistically significant) an 8-year follow-up found development in 19% of the ADR patients (four of 21). This appeared to be pre-existing. Spontaneous fusion occurred in 22% of cases (six patients) in the 8-year study. These authors suggested that their results were equivocal in supporting the theory that ADR reduced adjacent segment disease. (Garrido, 2010) (Quan, 2011) A recent comparison study found there was no significant difference between development of adjacent segment degeneration between ADR and fusion at a median follow-up of 37 months. The development is significantly higher in patients with concurrent DDD in the spine. Presence of osteopenia increases the risk. The authors also found that patients with
concurrent lumbar spine degenerative disease also had a higher risk. (Jawahar, 2010) (Nunley, 2011) The current predicted rate of development of adjacent segment disease after ACDF is 13.6% at five years and 25.6% at 10 years of follow-up. See also Adjacent segment disease/degeneration (fusion).

Heterotopic ossification (HO): (Defined as undesirable bone formation outside the skeleton after ADR that precludes the motion preservation for which the artificial discs were designed). An additional problem that has been published in the literature is development of heterotopic ossification. There appears to be a positive relationship between occurrence of HO and loss of movement of the cervical artificial disc, speculated to be due to bridging osteophyte formation. The effect of this on adjacent segment degeneration has yet to be determined but it is speculated that when this occurs at the intervertebral space it limits function of the disc and can possibly cause compression of the neural tissue. HO appears to increase with time, especially in bilevel procedures. One group of authors has gone so far as to indicate that HO is an inevitable postoperative complication. (Yi, 2010) A genetic predisposition has been suggested, and disc design appears to have an effect. Other contributing factors proposed include tissue trauma during surgery, surgical technique (including removal of bone dust), design allowing soft tissue or bony ingrowth to the disc space, osteolysis related to wear debris of metal on polyethylene component (in discs with this design), and use of nonsteroidal anti-inflammatory drugs (for prophylaxis). (Yi, 2010) (Quan, 2011) Literature available is generally based on small subsets of IDE study patients, limiting power of the study and generalized interpretation. The incidence of HO after cervical TDR in the literature gives an upper range of as high as 76% for two-level procedures and 66% for single-level. A recent 8-year follow-up of the Bryan disc showed development in 48% of 27 operated segments with restricted range of motion in nine cases. Development was more likely in two-level procedures. In earlier studies HO was low-grade (less than grade 3), with the supposition that this is less likely to interfere with motion. Longer-terms studies have found development of HO at higher grades. Early studies found development to have little effect on outcome, with an explanation being that even in the worst case the functional result is similar to that of an interbody graft in an ACDF. In the 8-year study of the Bryan disc patients who developed HO findings showed a trend for slightly higher neck and arm pain analog scores (not statistically significant). (Quan, 2011) (Leung, 2005) (Heidecke, 2008) (Lee, 2010) (Tu, 2011) (Mehren, 2006)

Types of ADR devices: Cervical discs all share important characteristics including restoration of intervertebral disc height, allowing motion and decompression, with removal of disc material. Devices differ in terms of articulating surfaces (metal-on-metal or metal-on-plastic), and biomechanical properties (constrained, semi-constrained, or non-constrained).

Prestige Disc: On July 16, 2007 the FDA approved the Prestige® Cervical Disc System from Medtronic Sofamor Danek. (FDA, 2007) This is a two-piece prosthesis constructed of stainless steel, employing ball-in-groove articulation. In 2007 results were published of 541 patients with single-level disease enrolled in 32 sites comparing ADR replacement with the Prestige ST disc (276 patient) with ACDF (265 patients). Neurological success rate was significantly higher in the arthroplasty group at 24 months (92.8% vs. 84.3%, respectively) with similar success rates on other outcome measures. At the 24-month follow-up all joints in the treated group were mobile. Another comparison study at two years found no significant difference in clinical outcomes between ADR and fusion treated patients (AAOS, VAS, NDI, JOA, SF-36 and satisfactions scores). (Peng, 2011)
**Bryan Disc:** A single piece metal-on-polymer prosthesis (a later version of the Prestige disc). On 5/12/09, the FDA approved the Bryan Cervical Disc (Medtronic; Memphis, Tennessee) in patients who have failed at least 6 weeks of conservative therapy for intractable radiculopathy and/or myelopathy secondary to disc degeneration or herniation. In 2007 results were published comparing this disc to ACDF, the latter being considered “gold standard.” This was an FDA IDE trial. The results were limited to three sites (115 patients). At 24 months statistically significant improvement was found in the Neck Disability Index (NDI), the Neck Pain Score, and SF-36 Physical component scores. Arm pain relief was similar. The conclusion was that the prosthesis compared favorably. Two patients in both groups required ACDF for adjacent level disease. (Sasso, 2007) Later documentation, again reporting a 24-month follow-up, indicates this study was actually performed in 30 sites. Participants were now reported as 242 patients receiving the disc and 221 receiving an ACDF in this noninferiority trial. There was a 20% loss of patients following randomization (37 from the TDR group and 80 from ACDF). In addition, unblinding occurred as well as treatment crossover. Results showed a statistically significant decrease in both groups for NDI, with the ADR group showing a significantly improved score at 24 months (16.2 for disc and 19.2 for ACDF). Both of these scores fall into a moderate disability range. Neck pain score was significantly improved in the ADR group over ACDF scores (23 vs. 30.3, respectively). Arm pain was similar. Similar results were noted for SF-36, neurological success and return to work at 24 months. The ADR group returned to work earlier (41 day vs. 61 days). For the ADR group overall success rate was 80.4% vs. 71.8% for the ACDF group. (FDA, 2009) (Heller, 2009)

**ProDisc-C:** Constructed of two chromium-cobalt endplates with sagittal fins for fixation into the adjacent vertebral body and a fixed polyethylene core. In 2007 a limited study group (25 patients with cervical disc herniation) received either an ADR or ACDF. Segmental motion decreased in both groups, but was significantly higher in the ACDF group. This study was only extended to six months. (Nabhan, 2007) In 2009 results were published in a 2-year follow-up of an IDE trial comparing the ProDisc-C (106) to ACDF in patients (103) from one of 13 investigational sites. There was no demographic measured for ongoing litigation or workers’ compensation involvement, although pre-operatively 84.9% of the ACDF group and 82.5% of the TDR group were employed and at 24 months the numbers were 80% and 82.8%, respectively. In terms of medications approximately 48% of both groups were using schedule 2 and 3 drugs pre-operatively and this decreased to 13% in the fusion group and 11.2% of the TDR group. Results were similar in terms of VAS neck and arm pain and neurological success. Second surgeries were required by 8.5% fusion patients compared to 1.8% of TDR patients (p=0.033). Results show that at 24 months postoperatively, 84.4% of ProDisc-C patients achieved a more than or equal to 4 degrees of motion or maintained motion relative to preoperative baseline at the operated level. (Murrey, 2009)

**Mobi-C:** A prospective study of 76 patients with two-year follow-up has been published on this cervical disc. Of note, 85.5% of segments were mobile at 2 years. HO was stated as responsible for the fusion of 6/76 levels, but the presence of HO did not alter clinical outcome. Adjacent segment degeneration was found in 9.1% of patients. (Beaurain, 2009)

**Study Designs:** The general design the randomized controlled studies discussed is a non-inferiority design, one that is generally employed when a margin of inferiority for a new technology is accepted because it is offset by advantages (i.e. the new technology is less invasive or has lower cost). This is not the case for ADR. There are also problems with unblinding, high
dropout rates, exclusion of patients after randomization and unclear or no intention-to-treat analysis. Non-validated instruments have been utilized for outcomes.

**ADR in a workers’ comp population:** A subgroup analysis of workers’ compensation patients in the IDE trials of the Prestige and Bryan cervical arthroplasties has been published. The study population included 93 patients out of 1,004 total (9.2%). Preoperatively, 36.2% of arthroplasty patients and 32.6% of fusion patients were working. The total number of study-group patients that were working preoperatively was not given. At 24 months, 63% of the arthroplasty patients and 53% of the ACDF patients had returned to work (non-significant intergroup difference).

Again, the percentage of total study-group patients that returned to work was not given. Return to work was earlier for TDR patients (median of 101 days as compared to 222 days). This was not statistically significant when controlled for sex, study, and work status. As noted above in a Bryan disc study (the only comparison data available), the TDR total-study group returned to work at 41 days vs. 61 days for the arthroplasty group. ([Heller, 2009](#)) Pre-operative work status was a significant factor for patients eventually working after surgery. While the arthroplasty group returned to work earlier as compared to the fusion group this was only significant for 3 months. It was noted that the increase in return to work in the TDR group could have been secondary to less disability in these patients. Details about work were not given (including full vs. limited duty). ([Steinmetz, 2008](#))

Recent additional research: A recent technology assessment by the California Technology Assessment Forum (CTAF) recommended that cervical disc replacement does not meet CTAF criteria for improvement in health outcomes. A particular concern was that long-term outcomes were not available, particularly in terms of benefit in prevention of development of adjacent segment disease. ([Walsh, 2010](#)) In a review performed by Washington State Health Technology Clinical Committee published in 2009 findings showed that there were no statistical differences in pain relief or functional improvement between cervical ADR and fusion as measured at one to two years. Neurological success (defined to include maintenance and improvement in neurological function) was 78% for ADR and 67% for fusion (statistically significant). They noted that no cost studies have been performed. There was insufficient evidence to draw conclusions regarding safety and efficacy in populations outside those studied by the FDA. There was no mention of HO or adjacent segment disease. The cervical disc was approved when used for FDA indications at a single level and with no contraindications. ([Dettori, 2008](#)), The North American Spine Society evidence-based clinical guideline for treatment of cervical radiculopathy due to degenerative disorders suggested fusion and ADR were comparable treatments in the short-term for single level disease. They also noted that anterior cervical decompression was comparable to anterior fusion, producing similar clinical outcomes in the treatment of single-level cervical radiculopathy from degenerative disorders (grade of recommendation: B for both comparisons). ([Bono, 2011](#))

**ACOEM- LOW BACK CHAPTER**

Artificial disc replacement is not recommended as a treatment for chronic non-specific low back pain or any other spinal pain syndrome.

**ACOEM- CERVICAL CHAPTER**
Disc replacement is not recommended as a treatment for chronic non-specific cervical pain or other spinal pain syndrome.

There are quality studies of short to intermediate term durations of up to 3 years for treatment of cervical radiculopathy or myelopathy patients (see evidence table). However, there are no quality trials comparing disc replacement with non-operative treatments, particularly including a quality rehabilitation program. All 4 of the highest quality studies document superiority of the disc replacement over fusion particularly in the first 3 months, and at least one study documented trends towards earlier return to work in the disc replacement group. (Mummaneni 07) However, there are no quality studies comparing disc replacement with either simple discectomy or non-operative treatments. A few trials included two-levels with disc replacement, but not more than two levels. Cervical disc replacement is invasive, has adverse effects, is costly, but trends towards faster recovery and studies have now been reported out to 3 years of follow-up sufficient to warrant a recommendation for consideration of this treatment for select patients. In all published series and RCTs the indications for cervical disc replacement surgery were patients who were candidates for discectomy or anterior discectomy and fusion for radiculopathy with or without myelopathy, and not patients with non-specific cervical pain. Additional research including demonstrated long-term safety and efficacy would be needed prior to a recommendation in support.

REFERENCES

1. OFFICIAL DISABILITY GUIDELINES / LOW BACK & NECK CHAPTERS, 2013
2. ACOEM PRACTICE GUIDELINES, LOW BACK & CERVICAL CHAPTERS, 2013