



CLINICAL GUIDELINES

CMM-602: Cervical Total Disc Arthroplasty Guidelines

Version 1.0.2023
Effective May 31, 2023



eviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Requests for individuals with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician, specialist and/or individual's Primary Care Physician (PCP) may provide additional insight.

eviCore's Clinical Review Criteria ("CRC") and related content is made available for the limited uses of: reference; and individual use, only limited to facilitating the determination of medically necessary and appropriate clinical treatment by clinicians for specific delegated patients under their care. The CRC and related content is proprietary information of eviCore, and copyrighted to the full extent of the law. Except as expressly permitted, you may not modify, copy, reproduce, republish, upload, post, transmit, hyperlink to or from, or distribute in any way the CRC, nor may you sell, transfer, distribute, assign, lease, reproduce, or otherwise use the CRC in commerce, in a manner that competes with us or infringes upon our rights, or for any public or commercial endeavor without our prior and express written consent.

CPT® (Current Procedural Terminology) is a registered trademark of the American Medical Association (AMA). CPT® five digit codes, nomenclature and other data are copyright 2023 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values or related listings are included in the CPT® book. AMA does not directly or indirectly practice medicine or dispense medical services. AMA assumes no liability for the data contained herein or not contained herein.

Clinical guidelines for medical necessity review of Comprehensive Musculoskeletal Management Services.

CMM-602: Cervical Total Disc Arthroplasty**CMM-602.1: General Guidelines****CMM-602.2: Initial Primary Cervical Total Disc Arthroplasty****CMM-602.3: Failed Cervical Total Disc Arthroplasty Implant****CMM-602.4: Adjacent Segment Disease Secondary to Cervical Total Disc Arthroplasty****CMM-602.5: Non-Indications****CMM-602.6: Procedure (CPT®) Codes****CMM-602.7: References**

CMM-602.1: General Guidelines

Application of Guideline

- The determination of medical necessity for the performance of cervical total disc arthroplasty is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.

Urgent/Emergent Indications/Conditions

- The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies are required. The following criteria are **NOT** required for confirmed urgent/emergent conditions:
 - ◆ Provider-directed non-surgical management
 - ◆ Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)
- Urgent/emergent conditions for cervical total disc arthroplasty include **ANY** of the following:
 - ◆ Myelopathy or Cord signal changes on MRI due to cord compression
 - ◆ Central cord syndrome
 - ◆ Documentation of progressive neurological deficit on two separate physical examinations
 - ◆ **ANY** of the following due to a neurocompressive pathology
 - Motor weakness of grade 3/5 or less of specified muscle(s)
 - Rapidly progressive symptoms of motor loss
 - Bowel incontinence
 - Bladder incontinence/retention
 - ◆ Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

CMM-602.2: Initial Primary Cervical Total Disc Arthroplasty

Initial primary cervical total disc arthroplasty is considered **medically necessary** for **ANY** of the following conditions when **ALL** of the following are met:

Radiculopathy

- The patient is skeletally mature
- Cervical disc prosthesis approved by the FDA or for an FDA approved indication and in accordance with FDA labeling
- No previous surgeries at the operative level
- No prior fusion at an adjacent cervical level
- The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy.

- The planned implant(s) is/are for a single level or simultaneous two contiguous level replacement(s)
- The patient is a candidate for single-level or two level anterior cervical decompression(s) and interbody fusion(s)
 - ◆ Please see **CMM-601.2 Initial Primary Anterior Cervical Discectomy and Fusion (ACDF)**
- Subjective symptoms including **BOTH** of the following:
 - ◆ Significant level of pain on a daily basis defined as **EITHER** of the following:
 - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as ≥ 7
 - Severe, disabling, crippling, or incapacitating pain
 - ◆ Unrelenting radicular pain to shoulder girdle and/or upper extremity resulting in disability
- Objective physical examination findings including **ANY** of the following:
 - ◆ Dermatomal sensory deficit
 - ◆ Motor deficit (e.g. biceps, triceps weakness)
 - ◆ Reflex changes
 - ◆ Shoulder Abduction Relief Sign
 - ◆ Nerve root tension sign (e.g. Spurling's maneuver)
 - ◆ Unrelenting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
- Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
 - ◆ Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks
 - ◆ Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
 - ◆ Epidural steroid injection(s)/selective nerve root block(s)
- Absence of clinically significant cervical instability on resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal or lordosis or spondylolisthesis (e.g. > 3.5 mm subluxation/translation or > 11 degrees angulation/rotational difference) from that of either adjacent spinal level
- Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) and/or osteophytes that is concordant with the patient's symptoms **and** physical examination findings
- Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)

Myelopathy

- The patient is skeletally mature
- Cervical disc prosthesis approved by the FDA or for an FDA approved indication and in accordance with FDA labeling

- No previous surgeries at the operative level
- No prior fusion at an adjacent cervical level
- The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy.
- The planned implant(s) is/are for a single level or simultaneous two contiguous level replacement(s)
- The patient is a candidate for single-level or two level anterior cervical decompression(s) and interbody fusion(s)
 - ◆ Please see **CMM-601.2 Initial Primary Anterior Cervical Discectomy and Fusion (ACDF)**
- Subjective symptoms including **ANY** of the following:
 - ◆ Upper/lower extremity weakness, numbness, or pain
 - ◆ Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
 - ◆ Urinary urgency
 - ◆ Gait disturbance
 - ◆ New-onset bowel or bladder dysfunction
 - ◆ Frequent falls
- Objective physical examination findings including at least **TWO** of the following:
 - ◆ Grip and release test
 - ◆ Ataxic gait
 - ◆ Hyperreflexia
 - ◆ Hoffmann sign
 - ◆ Pathologic Babinski sign
 - ◆ Tandem walking test demonstrating ataxia
 - ◆ Inverted brachial radial reflex
 - ◆ Increased muscle tone or spasticity
 - ◆ Clonus
 - ◆ Myelopathic hand
- Absence of clinically significant cervical instability on resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal or lordosis or spondylolisthesis (e.g. > 3.5 mm subluxation/translation or > 11 degrees angulation/rotational difference) from that of either adjacent spinal level
- Recent (within 6 months) MRI/CT findings are concordant with the patient's symptoms **and** physical examination findings showing **EITHER** of the following:
 - ◆ MRI/CT identifies cervical spinal cord compression
 - ◆ MRI/CT identifies cervical spinal stenosis

CMM-602.3: Failed Cervical Total Disc Arthroplasty Implant

Please refer to the following for a revision of a failed cervical total disc arthroplasty to a cervical fusion:

- ◆ For Anterior Cervical Fusion refer to **CMM-601.5: ACDF Following Failed Cervical Disc Arthroplasty Surgery**
- ◆ For Posterior Cervical Fusion refer to **CMM 604.7: Posterior Cervical Fusion (with or without Decompression) Following Failed Cervical Disc Arthroplasty Surgery**

CMM-602.4: Adjacent Segment Disease Secondary to Cervical Total Disc Arthroplasty

Cervical total disc arthroplasty for adjacent segment disease secondary to cervical total disc arthroplasty is considered **medically necessary** for **ANY** of the following conditions when **ALL** of the associated criteria are met:

Radiculopathy

- The prior total disc arthroplasty procedure at an adjacent level was performed at least 6 months prior.
- The patient is skeletally mature
- Cervical disc prosthesis approved by the FDA or for an FDA approved indication and in accordance with FDA labeling
- No previous surgeries on the disc(s) involved
- The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy
- Subjective symptoms including **BOTH** of the following:
 - ◆ Significant level of pain on a daily basis defined as **EITHER** of the following:
 - Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) as ≥ 7
 - Severe, disabling, crippling, or incapacitating pain
 - ◆ Unrelenting radicular pain to shoulder girdle and/or upper extremity resulting in disability
- Objective physical examination findings including **ANY** of the following:
 - ◆ Dermatomal sensory deficit
 - ◆ Motor deficit (e.g. biceps, triceps weakness)
 - ◆ Reflex changes
 - ◆ Shoulder Abduction Relief Sign
 - ◆ Nerve root tension sign (e.g. Spurling's maneuver)
 - ◆ Unrelenting radicular pain to shoulder girdle and/or upper extremity without concordant objective physical examination findings
- Less than clinically meaningful improvement with at least **TWO** of the following unless contraindicated:
 - ◆ Prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks

- ◆ Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks
- ◆ Epidural steroid injection(s)/selective nerve root block(s)
- Recent (within 6 months) imaging studies of the cervical spine including flexion/extension lateral views demonstrate successful cervical total disc arthroplasty at the adjacent level
- Absence of clinically significant cervical instability on resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal or lordosis or spondylolisthesis (e.g. > 3.5 mm subluxation/translation or > 11)
- Recent (within 6 months) MRI/CT identifies nerve root impingement caused by herniated disc(s) or osteophytes that is concordant with the patient's symptoms **and** physical examination findings
- Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)

Myelopathy

- The patient is skeletally mature
- Cervical disc prosthesis approved by the FDA or for an FDA approved indication and in accordance with FDA labeling
- No previous surgeries on the disc(s) involved
- The planned implant(s) will be used in the reconstruction of cervical disc(s) at C3-C7, following discectomy
- Subjective symptoms including **ANY** of the following:
 - ◆ Upper/lower extremity weakness, numbness, or pain
 - ◆ Fine motor dysfunction (buttoning, handwriting, clumsiness of hands)
 - ◆ Gait disturbance
 - ◆ New-onset bowel or bladder dysfunction
 - ◆ Frequent falls
- Objective physical examination findings including at least **TWO** of the following:
 - ◆ Grip and release test
 - ◆ Ataxic gait
 - ◆ Hyperreflexia
 - ◆ Hoffmann sign
 - ◆ Pathologic Babinski sign
 - ◆ Tandem walking test demonstrating ataxia
 - ◆ Inverted brachial radial reflex
 - ◆ Increased muscle tone or spasticity
 - ◆ Clonus
 - ◆ Myelopathic hand

- Absence of clinically significant cervical instability on resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal or lordosis or spondylolisthesis (e.g. > 3.5 mm subluxation/translation or > 11)
- Recent (within 6 months) MRI/CT findings are concordant with the patient's symptoms **and** physical examination findings showing **EITHER** of the following:
 - ◆ MRI/CT identifies cervical spinal cord compression
 - ◆ MRI/CT identifies cervical spinal stenosis

CMM-602.5: Non-Indications

Not Medically Necessary

- Cervical total disc arthroplasty for degenerative disc disease as the sole indication is considered **not medically necessary**.
- Cervical total disc arthroplasty following a failed cervical total disc arthroplasty at the same level is considered **not medically necessary**.
- Cervical total disc arthroplasty performed without meeting the requirements listed in the General Guidelines and the specific procedure Indications sections (initial, adjacent segment disease, and following failed cervical disc arthroplasty) is considered **not medically necessary**.

Experimental, Investigational, or Unproven (EIU)

- Cervical total disc arthroplasty is considered **experimental, investigational, or unproven (EIU)** when **ANY** of the following are present:
 - ◆ Patient is under age 18 or over age 60
 - ◆ Any prior surgery at the operative level
 - ◆ The planned procedure includes the combined use of a prosthesis and spinal fusion
 - ◆ A prior fusion at an adjacent cervical level
 - ◆ The planned procedure will lead to cervical total disc arthroplasty at more than two (2) levels
 - ◆ The planned procedure involves 2 or more levels that are not contiguous
 - ◆ Decreased bone mineral density defined by a T-score less than (worse than) -1.5 on a previous dual energy X-ray absorptiometry (DEXA) scan.
 - ◆ Allergy or sensitivity to titanium, aluminum or vanadium
 - ◆ Chronic non-specific neck or arm pain of unknown etiology
 - ◆ Absence of radiculopathy or myelopathy
 - ◆ Active systemic infection
 - ◆ Revision of an infected cervical disc arthroplasty
 - ◆ Rheumatoid arthritis or other autoimmune disease
 - ◆ Paget's disease, osteomalacia or any other metabolic bone disease
 - ◆ Severe poorly controlled diabetes mellitus requiring insulin treatment
 - ◆ There is radiological evidence of **ANY** of the following:
 - Clinically significant cervical instability on resting or lateral flexion/extension plain X-rays, defined as kyphotic deformity/significant reversal of lordosis or

- spondylolisthesis (e.g. > 3.5 mm subluxation/translation or > 11 degrees angulation/rotational difference) from that of either adjacent spinal level
- Significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g. ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma)
 - Spinal metastases
 - Severe spondylosis at the level to be treated characterized by bridging osteophytes, marked reduction or absence of motion, or collapse of the intervertebral disc space of greater than 50% of its normal height
 - Severe facet joint arthropathy
 - Ossification of the posterior longitudinal ligament (OPLL)

CMM-602.6: Procedure (CPT®) Codes

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

CPT®	Code Description/Definition
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), single interspace, cervical
+22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection), second level, cervical (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
+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)

This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

CMM-602.7: References

1. Acosta FL, Ames CP. Cervical Disc Arthroplasty: General Information. *Neurosurg Clin North Am.* 2005; (16): 603-607.
2. Ahrens M, Tsantrizos A, Donkersloot P, Martens F, Lauweryns P, Le Huec JC, et al. Nucleus replacement with the DASCOR disc arthroplasty device: interim two-year efficacy and safety results from two prospective, non-randomized multicenter European studies. *Spine (Phila Pa 1976).* 2009 Jun 1;34(13):1376-1384.
3. Ament JD, Yang Z, Nunley P, Stone MB, Kim KD. Cost-effectiveness of cervical total disc replacement vs fusion for the treatment of 2-level symptomatic degenerative disc disease. *JAMA Surg.* 2014 Dec; 149(12): 1231-1239.
4. American Academy of Orthopaedic Surgeons (AAOS). *Technology Overview. Cervical Disc Arthroplasty.* March 2010.
5. Anderson PA, Sasso RC, Riew KD. Comparison of adverse events between the Bryan artificial cervical disc and anterior cervical arthrodesis. *Spine.* 2008 May 20;33(12):1305-1312.
6. Auerbach JD, Jones KJ, Fras CI, Balderston JR, Rushton SA, Chin KR. The prevalence of indications and contraindications to cervical total disc replacement. *Spine J.* 2008 Sep-Oct;8(5):711-716.
7. Bao Q-B, Yuan HA. Artificial disc technology. *Neurosurg Focus.* 2000;9(4): Article 14.
8. Barbagallo GM, Assietti R, Corbino L, Olindo G, Foti PV, Russo V, Albanese V. Early results and review of the literature of a novel hybrid surgical technique combining cervical arthrodesis and disc arthroplasty for treating multilevel degenerative disc disease: opposite or complementary techniques? *Eur Spine J.* 2009 Jun;18 Suppl 1:29-39.
9. Bartels RH, Donk R, Verbeek AL. No justification for cervical disk prostheses in clinical practice: a meta-analysis of randomized controlled trials. *Neurosurgery.* 2010 Jun;66(6):1153-1160.
10. Bertagnoli R, Duggal N, Pickett GE, Wifigield CC, Gill SS, Karg A, Voigt S. Cervical total disc replacement, part two: clinical results. *Orthop Clin North Am.* 2005;36:355-362.
11. Bond M, McIntosh G, Fisher C et al. Treatment of Mild Cervical Myelopathy. *Spine (Phila Pa 1976).* 2019;44(22):1606-1612. doi:10.1097/brs.0000000000003124.
12. Boselie TF, Willems PC, van Mameren H, de Bie R, Benzel EC, van Santbrink H. Arthroplasty versus fusion in single-level cervical degenerative disc disease. *Cochrane Database Syst Rev.* 2012 Sep 12;9:CD009173. doi: 10.1002/14651858.CD009173.pub2.
13. BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC). Artificial vertebral disc replacement. *TEC Assessment Program.* June 2007. Vol. 22, No. 2.
14. BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC). Artificial intervertebral disc arthroplasty for treatment of degenerative disc disease of the cervical spine. *TEC Assessment Program.* November 2007 Vol. 22, No. 12. Republished August 2009, Vol. 24, No. 3.
15. Blumenthal SL, Ohnmeiss DD, Guyer RD, et al. Reoperations in cervical total disc replacement compared with anterior cervical fusion: results compiled from multiple prospective food and drug administration investigational device exemption trials conducted at a single site. *Spine.* 2013; 38: 1177-1182.
16. Blumenthal SL, Ohnmeiss DD, Guyer RD, Hochschuler SH. Prospective study evaluating total disc replacement: preliminary results. *J Spinal Disord Tech.* 2003 Oct;16(5):450-454.
17. Blumenthal SL, Ohnmeiss DD, Guyer R, Hochschuler S, McAfee P, Garcia R, Salib R, Yuan H, Lee C, Bertagnoli R, Bryan V, Winter R. Artificial intervertebral disks and beyond: a North American Spine Society Annual Meeting Symposium. *Spine J.* Nov-Dec 2002;2(6):460-463.
18. Boselie TF, Willems PC, van Mameren H, de Bie R, Benzel EC, van Santbrink H. Arthroplasty versus fusion in single-level cervical degenerative disc disease. *Cochrane Database Syst Rev.* 2012 Sep 12;9:CD009173.
19. Boswell MV, Shah RV, Everett CR, et al. Interventional techniques in the management of chronic spinal pain: evidence-based practice guidelines. *Pain Phys.* 2005;8:1-47.
20. Bryan VE. Cervical motion segment replacement. *Eur Spine J.* 2002 Oct;11 Suppl 2:S92-7. Epub 2002 Sep 12.
21. Burkus JK, Haid RW, Traynelis VC, Mummaneni PV. Long-term clinical and radiographic outcomes of cervical disc replacement with the Prestige disc: results from a prospective randomized controlled clinical trial. *J Neurosurg Spine.* 2010 Sep;13(3):308-318.
22. California Technology Assessment Forum (CTAF). *Artificial disc replacement for degenerative disc disease of the cervical spine.* Updated Oct 2009.
23. Cepoiu-Martin M, Faris P, Lorenzetti D, Prefontaine E, Noseworthy T, Sutherland L. Artificial cervical disc arthroplasty: a systematic review. *Spine (Phila Pa 1976).* 2011 Dec 1;36(25):E1623-633.
24. Chatley A, Kumar R, Jain V, Behari S, Sahu R. Effect of spinal cord signal intensity changes on clinical outcome after surgery for cervical spondylotic myelopathy. *J Neurosurg Spine.* 2009;11(5):562-567. doi:10.3171/2009.6.spine091.
25. Chen J, Fan SW, Wang XW, Yuan W. Motion analysis of single-level cervical total disc arthroplasty: a meta-analysis. *Orthop Surg.* 2012 May;4(2):94-100.
26. Cheng L, Nie L, Hou Y. Fusion versus Bryan cervical disc in two-level cervical disc disease: a prospective, randomized study. *Int Orthop.* 2009 Oct;33(5):1347-51.

27. Coric D, Cassis J, Carew JD, Boltes MO. Prospective study of cervical arthroplasty in 98 patients involved in 1 of 3 separate investigational device exemption studies from a single investigational site with a minimum 2-year follow-up. Clinical article. *J Neurosurg Spine*. 2010 Dec;13(6):715-721.
28. Coric D, Nunley PD, Guyer RD, Musante D, Carmody CN, Gordon CR, Lauryssen C, Ohnmeiss DD, Boltes MO. Prospective, randomized, multicenter study of cervical arthroplasty: 269 patients from the Kineflex|C artificial disc investigational device exemption study with a minimum 2-year follow-up: clinical article. *Neurosurg Spine*. 2011 Oct;15(4):348-58.
29. Cunningham MR, Hershman S, Bendo J. Systematic review of cohort studies comparing surgical treatments for cervical spondylotic myelopathy. *Spine* 2010;35(5):537-543.
30. Davis RJ, Nunley PD, Kim KD, et al. Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results. *J Neurosurg Spine*. 2015; 22(1):15-25.
31. Davis RJ, Kim KD, Hisey MS, et al. Cervical total disc replacement with the Mobi-C cervical artificial disc compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled multicenter clinical trial: clinical article. *J Neurosurg Spine*. 2013; 19(5):532-545.
32. Delamarter RB, Bae HW, Pradhan BB. Clinical results of ProDisc-II lumbar total disc replacement: report from the United States Clinical Trial. *Orthop Clin N Am*. 2005;36:301-13.
33. Delamarter RB, Murrey D, Janssen ME, et al. Results at 24 months from the prospective, randomized, multicenter Investigational Device Exemption trial of ProDisc-C versus anterior cervical discectomy and fusion with 4-year follow-up and continued access patients. *SAS J*. 2010;4:122-128.
34. Delamarter R, Zigler JE, Balderston RA, Cammisa FP, Goldstein JA, Spivak JM. Prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement compared with circumferential arthrodesis for the treatment of two-level lumbar degenerative disc disease: results at twenty-four months. *J Bone Joint Surg Am*. 2011 Apr 20;93(8):705-715. Epub 2011 Mar 11.
35. Ding C, Hong Y, Liu H, Shi R, Hu T, Li T. Intermediate clinical outcome of Bryan Cervical Disc replacement for degenerative disk disease and its effect on adjacent segment disks. *Orthopedics*. 2012 Jun;35(6):e909-e916.
36. Durbhakula MM, Ghiselli G. Cervical Total Disc Replacement, Part I: Rationale, Biomechanics, and Implant Types. *Orthop Clin North Am*. 2005 Jul;36(3):349-354.
37. ECRI Institute. *Artificial intervertebral disc replacement (AIDR) for lumbar degenerative disc disease (DDD). Emerging Technology Evidence Report*. Plymouth Meeting (PA): ECRI Institute; 2009a October 14.
38. ECRI Institute. *Artificial intervertebral disc replacement for symptomatic cervical disc disease. Emerging Technology Evidence Report*. Plymouth Meeting (PA): ECRI Institute; June 5, 2009b.
39. ECRI Institute. *Artificial intervertebral disc replacement for cervical disc disease. Evidence report*. September 2012. Plymouth Meeting (PA): ECRI Institute; September 2012.
40. Farshad M, Burgstaller JM, Held U, et al. Do preoperative corticosteroid injections increase the risk for infections or wound healing problems after spine surgery? *Spine*. 2018;43(15): 1089-1094.
41. Food and Drug Administration (FDA) Summary of Safety and Effectiveness Data *Artificial Cervical Disc. M6-C™ Artificial Cervical Disc*.
42. Food and Drug Administration (FDA). *Prestige® LP Cervical Disc*.
43. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). New Device Approval: Simplify® Cervical Artificial Disc- P200022. Issued September 18, 2020. Fekete TF, Porchet F. Overview of disc arthroplasty-past, present and future. *Acta Neurochir Wien*. 2010 Mar;152(3):393-404.
44. Gandhi AA, Kode S, DeVries NA, Grosland NM, Smucker JD, Fredericks DC. Biomechanical Analysis of Cervical Disc Replacement and Fusion Using Single Level, Two Level and Hybrid Constructs. *Spine*. 2015 Oct; 15 (40): 1578-1585. doi:10.1097/BRS. 0000000000001044.
45. Garrido BJ, Taha TA, Sasso RC. Clinical outcomes of Bryan cervical disc arthroplasty a prospective, randomized, controlled, single site trial with 48-month follow-up. *J Spinal Disord Tech*. 2010 Aug;23(6):367-371.
46. Goffin J, van Loon J, Van Calenbergh F, Lipscomb B. A clinical analysis of 4- and 6-year follow-up results after cervical disc replacement surgery using the Bryan Cervical Disc Prosthesis. *J Neurosurg Spine*. 2010 Mar;12(3):261-269.
47. Gornet MF, Schranck FW, Copay AG, Kopjar B. The Effect of Workers' Compensation Status on Outcomes of Cervical Disc Arthroplasty. *J Bone Joint Surg Am*. 2016; 98:93-99
48. Grob D, Porchet F, Kleinstück FS, Lattig F, Jeszenszky D, Luca A, Mutter U, Mannion AF. A comparison of outcomes of cervical disc arthroplasty and fusion in everyday clinical practice: surgical and methodological aspects. *Eur Spine J*. 2010 Feb;19(2):297-306.
49. Heidecke V, Burkert W, Brucke M, Rainov NG. Intervertebral disc replacement for cervical degenerative disease-clinical results and functional outcome at two years in patients implanted with the Bryan cervical disc prosthesis. *Acta Neurochir Wien*. 2008 May;150(5):453-459; discussion 459. Epub 2008 Apr 20.
50. Heller JG, Sasso RC, Papadopoulos SM, Anderson PA, Fessler RG, Hacker RJ, Coric D, Cauthen JC, Riew DK. Comparison of BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion: clinical and radiographic results of a randomized, controlled, clinical trial. *Spine (Phila Pa 1976)*. 2009 Jan 15;34(2):101-107.

51. Hills BB, Kasliwal MK. Cervical Radiographic Parameters in the Management of Cervical Spine Disorders: The Minimum that Needs to Be Measured. *SpineLine*. 2019 September/October; 12-16.
52. Huang RC, Girardi FP, Lim MR, Cammisa FP. Advantages and disadvantages of nonfusion technology in spine surgery. *Orthop Clin N Am*. 2005;36:263-239.
53. Huppert J, Beaurain J, Steib JP, Bernard P, Dufour T, Hovorka I, Stecken J, Dam-Hieu P, Fuentes JM, Vital JM, Vila T, Aubourg L. Comparison between single- and multi-level patients: clinical and radiological outcomes 2 years after cervical disc replacement. *Eur Spine J*. 2011 Sep;20(9):1417-1426. Epub 2011 Feb 20.
54. International Society for the Advancement of Spine Surgery (ISASS). Position Statement: Cervical Total Disc Arthroplasty. Approved October 2009.
55. Jackson RJ¹, et al. Subsequent surgery rates after cervical total disc replacement using a Mobi-C Cervical Disc Prosthesis versus anterior cervical discectomy and fusion: a prospective randomized clinical trial with 5-year follow-up. *J Neurosurg Spine*. 2016 Jan 22:1-12.
56. Jacob K, Patel M, Parsons A et al. Level-specific Perioperative and Clinical Outcome Comparison: Cervical Disk Replacement Versus Anterior Cervical Discectomy and Fusion at C5-C6 in Patients With Myeloradiculopathy. *JAAOS*. 2022;30(17):e1137-e1147. doi:10.5435/jaaos-d-21-01276.
57. Janssen ME, Zigler JE, Spivak JM, et al. ProDisc-C total disc replacement versus anterior cervical discectomy and fusion for single-level symptomatic cervical disc disease: seven-year follow-up of the prospective randomized U. S. Food and Drug Administration investigational device exemption study. *J Bone Joint Surg Am*. 2015; 97: 1738-1747.
58. Jawahar A, Cavanaugh DA, Kerr EJ 3rd, Birdsong EM, Nunley PD. Total disc arthroplasty does not affect the incidence of adjacent segment degeneration in cervical spine: results of 93 patients in three prospective randomized clinical trials. *Spine J*. 2010 Dec;10(12):1043-8. Epub 2010 Sep 24.
59. Johansen TO, Sundseth J, Fredrikli OA, et al. Effect of arthroplasty vs fusion for patients with cervical radiculopathy: a randomized clinical trial. *JAMA Netw Open*. 2021;4(8):e2119606. doi:10.1001/jamanetworkopen. 2021.19606.
60. Kalsi-Ryan, S, et al. Ancillary Outcomes Measures for Assessment of Individuals with Cervical Spondylotic Myelopathy. *Spine*. 2013 Oct; 38 (22S) Supplement 1:S111-S122.
61. Kim K, Hoffman G, Bae H et al. Ten-Year Outcomes of 1- and 2-Level Cervical Disc Arthroplasty From the Mobi-C Investigational Device Exemption Clinical Trial. *Neurosurgery*. 2021;88(3):497-505. doi:10.1093/neuros/nyaa459.
62. Kim SW, Limson MA, Kim SB, Arbatin JJ, Chang KY, Park MS, Shin JH, Ju YS. Comparison of radiographic changes after ACDF versus Bryan disc arthroplasty in single and bi-level cases. *Eur Spine J*. 2009 Feb;18(2):218-231.
63. Kostuik JP. Intervertebral disk replacement. Experimental study. *Clin Orthop Relat Res*. 1997 Apr;337:27-41.
64. Kurtz SM, Pelozo J, Siskey R, Villarraga ML. Analysis of a retrieved polyethylene total disc replacement component. *Spine J*. 2005 May-Jun;5(3):344-350.
65. Kurtz SM, van Ooij A, Ross R, Malefit JdW, Pelozo J, Ciccarelli L, Villarraga ML. Polyethylene wear and rim fracture in total disc arthroplasty. *Spine J*. 2007;7:12-21.
66. Lafuente J, Casey ATH, Petzold A, Brew S. The Bryan cervical disc prosthesis as an alternative to arthrodesis in the treatment of cervical spondylosis. *J Bone Joint Surg Br*. 2005;87(B):508-512.
67. Lanman T, Burkus J, Dryer R, Gornet M, McConnell J, Hodges S. Long-term clinical and radiographic outcomes of the Prestige LP artificial cervical disc replacement at 2 levels: results from a prospective randomized controlled clinical trial. *J Neurosurg Spine*. 2017;27(1):7-19. doi:10.3171/2016.11.spine16746.
68. Loidolt T, Kurra S, Riew K, Levi A, Florman J, Lavelle W. Comparison of adverse events between cervical disc arthroplasty and anterior cervical discectomy and fusion: a 10-year follow-up. *Spine J*. 2021;21(2):253-264. doi:10.1016/j.spinee.2020.10.013.
69. Martin CW and the Work Comp Board (WCB) Evidence Based Practice Group. *Artificial cervical and lumbar disc implants: a review of the literature*. Apr 2005.
70. McAfee PC, Reah C, Gilder K, Eisermann L, Cunningham B. A Meta-Analysis of Comparative Outcomes Following Cervical Arthroplasty or Anterior Cervical Fusion: Results from Four Prospective Multi-center Randomized Clinical Trials and up to 1226 Patients. *Spine (Phila Pa 1976)*. 2011 Oct 27.
71. Mummaneni PV, Burkus JK, Haid RW, Traynelis VC, Zdeblick TA. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. *J Neurosurg Spine*. 2007;6:198-209.
72. Murrey D, Janssen M, Delamarter R, Goldstein J, Zigler J, Tay B, Darden B. Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. *Spine J*. 2009 Apr;9(4):275-86.
73. Nabhan A, Ahlhelm F, Shariat K, Pitzen T, Steimer O, Steudel W-I, Pape D. The ProDisc-C Prosthesis: Clinical and radiological experience 1 year after surgery. *Spine*. 2007;32(18):1935-41.
74. National Institutes for Health and Clinical Excellence (NICE). *Prosthetic intervertebral disc replacement in the cervical spine*. Interventional Procedure Guidance 341. May 2010.

75. National Institutes for Health and Clinical Excellence (NICE). *Prosthetic intervertebral disc replacement in the lumbar spine*. Interventional Procedure Guidance 306. Revised July 2009.
76. North American Spine Society (NASS) *Coverage Policy Recommendations. Cervical Artificial Disc Replacement*. 2014.
77. Nunley P, Frank K, Stone M. Patient Selection in Cervical Disc Arthroplasty. *Int J Spine Surg*. 2020 Aug;14(s2):S29-S35. doi: 10.14444/7088.
78. Nunley PD, Jawahar A, Kerr EJ 3rd, Gordon CJ, Cavanaugh DA, Birdsong EM, Stocks M, Danielson G. Factors affecting the incidence of symptomatic adjacent-level disease in cervical spine after total disc arthroplasty: 2- to 4-year follow-up of 3 prospective randomized trials. *Spine (Phila Pa 1976)*. 2012 Mar 15;37(6):445-51.
79. Ontario Health Technology Assessment Committee (OHTAC). OHTAC Recommendation: Updated Health Technology Policy Assessment (HPTA) on Artificial Disc Replacement for Lumbar and Cervical Degenerative Disc Disease. Updated Apr 2006. *Ont Health Technol Assess Ser*. 2006;6(10):1-98.
80. Papadopoulos S. The Bryan Cervical Disc System. *Neurosurg Clin North Am*. 2005;16:629-636.
81. Peng-Fei A, Yu-Hua J. Cervical disc prosthesis replacement and interbody fusion—a comparative study. *Int Orthop*. 2006 Dec 16.
82. Peng-Fei S, Yu-Hua J. Cervical disc prosthesis replacement and interbody fusion: a comparative study. *Int Orthop*. 2008 Feb;32(1):103-106. Epub 2006 Dec 16.
83. Phillips F, Allen T, Regan J et al. Cervical Disc Replacement in Patients With and Without Previous Adjacent Level Fusion Surgery: A prospective study. *Spine (Phila Pa 1976)*. 2009;34(6):556-565. doi:10.1097/brs.0b013e31819b061c.
84. Phillips FM, Garfin SR. Cervical Disc Replacement. *Spine*. 2005;30(17S):S27-33.
85. Phillips F, Geisler F, Gilder K, Reah C, Howell K, McAfee P. Long-term Outcomes of the US FDA IDE Prospective, Randomized Controlled Clinical Trial Comparing PCM Cervical Disc Arthroplasty With Anterior Cervical Discectomy and Fusion. *Spine (Phila Pa 1976)*. 2015;40(10):674-683. doi:10.1097/brs.0000000000000869.
86. Phillips F, Lee J, Geisler F et al. A Prospective, Randomized, Controlled Clinical Investigation Comparing PCM Cervical Disc Arthroplasty With Anterior Cervical Discectomy and Fusion. *Spine (Phila Pa 1976)*. 2013;38(15):E907-E918. doi:10.1097/brs.0b013e318296232f.
87. Phillips FM, Tzermiananos MN, Voronov LI, Havey RM, Carandang G, Dooris A, et al. Effect of two-level total disc replacement on cervical spine kinematics. *Spine (Phila Pa 1976)*. 2009 Oct 15;34(22):E794-E799.
88. Pickett GE, Rouleau JP, Duggal N. Kinematic Analysis of the Cervical Spine Following Implantation of an Artificial Cervical Disc. *Spine*. 2005;30(17):1949-54.
89. Porchet F, Metcalf NH. Clinical outcomes with the Prestige II cervical disc: preliminary results from a prospective randomized clinical trial. *Neurosurg Focus*. 2004;17(3): 36-43.
90. Pracyk JB, Traynelis VC. Treatment of the Painful Motion Segment: Cervical Arthroplasty. *Spine*. 2005;30(16S):S23-S32.
91. Quan GM, Vital JM, Hansen S, Pointillart V. Eight-year clinical and radiological follow-up of the Bryan cervical disc arthroplasty. *Spine (Phila Pa 1976)*. 2011 Apr 15;36(8):639-46.
92. Radcliff K, Coric D, Albert T. Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial. *J Neurosurg Spine*. 2016;25(2):213-224. doi:10.3171/2015.12.spine15824.
93. Ren X, Wang W, Chu T, Wang J, Li C, Jiang T. The intermediate clinical outcome and its limitations of Bryan cervical arthroplasty for treatment of cervical disc herniation. *J Spinal Disord Tech*. 2011 Jun;24(4):221-229.
94. Riina J, Patel A, Dietz JW, Hoskins JS, Trammell TR, Schwartz DD. Comparison of single-level cervical fusion and a metal-on-metal cervical disc replacement device. *Am J Orthop*. 2008 Apr;37(4):E71-7.
95. Rihn JA, Harrod C, Albert TJ. Revision cervical spine surgery. *Orthopedic Clinics of North America* 2012;43(1):123-136.
96. Robertson JT, Metcalf NH. Long-term outcome after implantation of the Prestige I disc in an end-stage indication: 4-year results from a pilot study. *Neurosurg Focus*. 2004;17(3):69-71.
97. Robertson JT, Papadopoulos SM, Traynelis VC. Assessment of adjacent-segment disease in patients treated with cervical fusion or arthroplasty: a prospective 2-year study. *J Neurosurg Spine*. 2005;(3):417-23.
98. Ryu KS, Park CK, Jun SC, Huh HY. Radiological changes of the operated and adjacent segments following cervical arthroplasty after a minimum 24-month follow-up: comparison between the Bryan and Prodisc-C devices. *J Neurosurg Spine*. 2010 Sep;13(3):299-307.
99. Salari B, McAfee PC. Cervical total disk replacement: complications and avoidance. *Orthop Clin North Am*. 2012 Jan;43(1):97-107, ix.
100. Sasso RC, Anderson PA, Riew KD, Heller JG. Results of cervical arthroplasty compared with anterior discectomy and fusion: four-year clinical outcomes in a prospective, randomized controlled trial. *J Bone Joint Surg Am*. 2011 Sep 21;93(18):1684-1692.
101. Sasso RC, Best NM. *Cervical kinematics after fusion and BRYAN disc arthroplasty*. *J Spinal Disord Tech*. 2008b Feb;21(1):19-22.

102. Sasso RC, Best NM, Metcalf NH, Anderson PA. Motion analysis of BRYAN cervical disc arthroplasty versus anterior discectomy and fusion: results from a prospective, randomized, multicenter, clinical trial. *J Spinal Disord Tech*. 2008a Aug;21(6):393-399.
103. Sasso RC, Smucker JD, Hacker RJ, Heller JG. Artificial disc versus fusion: a prospective, randomized study with 2-year follow-up on 99 patients. *Spine*. 2007b Dec 15;32(26):2933-2940; discussion 2941-2942.
104. Sasso RC, Smucker JD, Hacker RJ, Heller JG. Clinical Outcomes of BRYAN Cervical Disc Arthroplasty: A Prospective, Randomized, Controlled, Multicenter Trial With 24-month Follow-up. *J Spinal Disord Tech*. 2007a;20:481-491.
105. Schuessmann E, Aghayev E, Staub L, Moulin P, Zweig T, Röder C; SWISSspine Registry Group. SWISSspine: the case of a governmentally required HTA-registry for total disc arthroplasty: results of cervical disc prostheses. *Spine (Phila Pa 1976)*. 2010 Nov;35(24):E1397-E1405.
106. Sekhon LHS, Duggal N, Lynch JJ, et al. *Magnetic Resonance Imaging Clarity of the Bryan®, Prodisc-C®, Prestige LP®, and PCM® Cervical Arthroplasty Devices*.
107. Sharan AD, Goldstein JA. *Cervical artificial disc replacement technologies*. Updated Aug 2015.
108. Shim DA, Yi S, Yoon DH, Him KN, Shin HC. Artificial disc replacement combined with fusion versus two-level fusion in cervical two-Level disc disease. *Spine*. 2009 May; 34 (11): 1153-1159
109. Shim CS, Lee S-H, Shin H. Versus ProDisc: A Comparative Study of a Minimum 3-Year Follow-up. *Spine*. 2007;32(9):1012-1018.
110. Shriver MF, Lubelski D, Sharma AM, Stenimetz MP, Benzel EC, Mroz TE. Adjacent segment degeneration and disease following cervical arthroplasty: a systematic review and meta-analysis. *Spine J*. 2016 Feb; 16(2): 168-181.
111. Thayer L, Tiffany E, Carreira D. Addressing Smoking in Musculoskeletal Specialty Care. *J Bone Joint Surg Am*. 2021;103(22):2145-2152. doi:10.2106/jbjs.21.00108.
112. Traynelis VC and Treharne RW. Use of the Prestige® LP Artificial Cervical Disc in the spine. *Expert Rev Med Devices*. 2007;4(4):437-440.
113. Upadhyaya CD, Wu JC, Trost G, et al. Analysis of the three United States Food and Drug Administration investigational device exemption cervical arthroplasty trials. *J Neurosurg Spine*. 2012 Mar;16(3):216-228. Epub 2011 Dec 23.
114. Uschold TD, Fusco D, Germain R, Tumialan LM, Chang SW. Cervical and Lumbar Spinal Arthroplasty: Clinical Review. *AJNR*. 2011 Oct 27. [Epub ahead of print].
115. U.S. Food and Drug Administration. *Orthopaedic and Rehabilitation Devices*. Panel of the Medical Devices Advisory Committee. Nov 2002. Updated Nov 2002.
116. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). *New Device Approval: ProDisc™ -C Total Disc Replacement-P070001/S001*. Issued December 17, 2007.
117. U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). *New Device Approval: Charite™ Artificial Disc-P040006*. Issued October 26, 2004. Updated March 9, 2005.
118. Walraevens J, Demaerel P, Suetens P, et al. Longitudinal prospective long-term radiographic follow-up after treatment of single-level cervical disk disease with the Bryan Cervical Disc. *Neurosurgery*. 2010 Sep;67(3):679-687; discussion 687.
119. Wang G. *Health Technology Assessment: Artificial Disc Replacement*. Washington State Department of Labor and Industries. Updated Nov 2004.
120. Weinberg D, Chugh AJ, Gebhart JJ, et al. Magnetic resonance imaging of the cervical spine under-represents sagittal plane deformity in degenerative myelopathy patients. *Int J Spine Surg*. 2016;10:32.doi: 10.14444/3032.
121. Willems PC, Elmans L, Anderson PG, van der Schaaf DB, de Kleuver M. Provocative Discography and Lumbar Fusion. *Spine*. 2007;32(10):1094-1099.
122. Wu JC, Huang WC, Tsai TY, Fay LY, Ko CC, Tu TH, Wu CL, Cheng H. Multilevel Arthroplasty for Cervical Spondylosis: More Heterotopic Ossification at 3 Years of Follow-up. *Spine (Phila Pa 1976)*. 2012 Sep 15;37(20):E1251-E1259.
123. Yajun W, Yue Z, Xiuxin H, Cui C. A meta-analysis of artificial total disc replacement versus fusion for lumbar degenerative disc disease. *Eur Spine J*. 2010 Aug;19(8):1250-1261. Epub 2010 Apr 4.
124. Yang YC, Nie L, Cheng L, Hou Y. Clinical and radiographic reports following cervical arthroplasty: a 24-month follow-up. *Int Orthop*. 2009 Aug;33(4):1037-1042.
125. Yang S, Wu X, Hu Y, Li J, Liu G, Xu W, Yang C, Ye S. Early and intermediate follow-up results after treatment of degenerative disc disease with the Bryan cervical disc prosthesis: single- and multiple-level. *Spine*. 2008 May 20;33(12):E371-E377.
126. Yang B, Li H, Zhang T, He X, Xu S. The incidence of adjacent segment degeneration after cervical disc arthroplasty (CDA): a meta analysis of randomized controlled trials. *PLoS One*. 2012;7(4):e35032.
127. Yi S, Kim KN, Yang MS, Yang JW, Kim H, Ha Y, Yoon do H, Shin HC. Difference in occurrence of heterotopic ossification according to prosthesis type in the cervical artificial disc replacement. *Spine (Phila Pa 1976)*. 2010 Jul 15;35(16):1556-1561.

128. Yi S, Lee DY, Ahn PG, Kim KN, Yoon do H, Shin HC. Radiologically documented adjacent-segment degeneration after cervical arthroplasty: characteristics and review of cases. *Surg Neurol*. 2009 Oct;72(4):325-329; discussion 329.
129. Yin L, Zhang J, Wu Y, Li J, Yang Q. Increased signal intensity of spinal cord on T2W magnetic resonance imaging for cervical spondylotic myelopathy patients. *Medicine (Baltimore)*. 2020;99(49):e23098. doi:10.1097/md.00000000000023098.
130. Zhao YB, Sun Y, Chen ZQ, Liu ZJ. Application of cervical arthroplasty with Bryan cervical disc: long-term X-ray and magnetic resonance imaging follow-up results. *Chin Med J Engl*. 2010 Nov;123(21):2999-3002.
131. Zeller JL. Artificial spinal disk superior to fusion for treating degenerative disk disease. *JAMA*. 2006;296(22):2665-2666.
132. Zhang X, Zhang X, Chen C, Zhang Y, Wang Z, Wang B, Yan W, Li M, Yuan W, Wang Y. Randomized, Controlled, Multicenter, Clinical Trial Comparing BRYAN Cervical Disc Arthroplasty with Anterior Cervical Decompression and Fusion in China. *Spine (Phila Pa 1976)*. 2011 Jun 13.
133. Zigler JE, Delamarter R, Murrey D, Spivak J, Janssen M. ProDisc-C and ACDF as Surgical Treatment for Single Level Cervical Symptomatic Degenerative Disc Disease: Five-Year Results of an FDA Study. *Spine (Phila Pa 1976)*. 2012 Oct 17. [Epub ahead of print]
134. Zigler JE. Clinical results with ProDisc: European experience and U.S. Investigation Device Exemption Study. *Spine*. 2003;28(20S):S163-S166.
135. Zindrick M, Harris MB, Humphreys SC, et.al. Cervical disc arthroplasty. *J Am Acad Orthop Surg*. Oct 2010;18(10):631-637.