



Comparative Effectiveness Review
Number 266

Cervical Degenerative Disease Treatment: A Systematic Review



Cervical Degenerative Disease Treatment: A Systematic Review

Prepared for:

Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No. 75Q80120D00006

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AHRQ appreciates appropriate acknowledgment and citation of its work. Suggested language for acknowledgment: This work was based on an evidence report, Cervical Degenerative Disease Treatment: A Systematic Review, by the Evidence-based Practice Center Program at the Agency for Healthcare Research and Quality (AHRQ).

Suggested citation: Selph SS, Skelly AC, Jungbauer RM, Brodt E, Blazina I, Philipp TC, Mauer KM, Dettori J, Atchison C, Riopelle D, Stabler-Morris S, Fu R, Yu Y, Chou R. Cervical Degenerative Disease Treatment: A Systematic Review. Comparative Effectiveness Review No.

266. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 75Q80120D00006.) AHRQ Publication No. 24-EHC001. Rockville, MD: Agency for Healthcare Research and Quality; November 2023. DOI: <https://doi.org/10.23970/AHRQEPCER266>. Posted final reports are located on the Effective Health Care Program [search page](#).

Preface

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If you have comments on this systematic review, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Acknowledgments

The authors gratefully acknowledge the following individuals for their contributions to this project: Tracy Dana, M.L.S., Tamara Cheney, M.D., Jessica Griffin, M.S., and Tosha Zaback, M.P.H., from the Pacific Northwest Evidence-based Practice Center; Trish Rehring, M.P.H., from the Congress of Neurological Surgeons; Associate Editor Jaya K. Rao, M.D., M.S., at the Scientific Resource Center, Pacific Northwest EPC; and Task Order Officer Kim Wittenberg, M.A., at AHRQ.

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In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

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In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

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Cervical Degenerative Disease Treatment: A Systematic Review

Abstract

Objectives. Cervical degenerative disease (CDD) is common, becomes more prevalent with age, and is managed with surgical and nonoperative treatments to alleviate pain, improve function, and prevent progression or recurrence. This systematic review summarizes the evidence on treatments for CDD.

Data sources. We searched Ovid MEDLINE®, Embase®, and Cochrane CENTRAL from 1980 to February 15, 2023; reference lists; and clinical trial registries.

Review methods. Predefined criteria were used to identify studies; prespecified methods were used to assess study quality and strength of evidence for key outcomes. Effects were analyzed qualitatively and quantitatively where appropriate.

Results. We included 57 randomized controlled trials, 56 nonrandomized studies, and 1 systematic review. Studies enrolled patients with radiculopathy and/or myelopathy with disease at one or more levels. A variety of surgical approaches were used; there were few comparative studies of nonoperative treatments. Most studies were rated moderate risk of bias, while the majority of evidence was rated low or insufficient strength to draw conclusions on comparative benefits and harms.

Cervical arthroplasty versus anterior cervical discectomy and fusion (ACDF): In single-level disease, there were no important differences between cervical arthroplasty and ACDF in pain or function. Cervical arthroplasty was associated with a lower likelihood of reoperation and slightly lower likelihood of any serious adverse event (SAE) in the short term, with no difference between cervical arthroplasty and ACDF in SAEs longer term. In patients with 2-level disease, pain, function, and likelihood of reoperation at the index level were similar, but the likelihood of an adverse event was slightly lower at 24 months with cervical arthroplasty, with no difference at 120 months.

Anterior versus posterior approach: There was no difference between these approaches in pain, function, quality of life, and reoperation in patients with fewer than three operated levels. Limited evidence suggests that a posterior approach is associated with a greater likelihood of experiencing any SAE in patients with procedures at three or more levels.

Standalone cage versus plate and cage in ACDF: Fusion rates were similar between standalone cage versus plate and cage; there were no differences between treatments in postoperative arm pain, function, quality of life, or adjacent-level ossification.

Laminoplasty versus laminectomy and fusion. There was little difference between surgical techniques in postoperative function, but the risk of experiencing a complication was lower with laminoplasty, with no difference in reoperation rates.

Conclusions. There were few differences in benefits between surgical approaches and techniques for the treatment of CDD. However, there were some differences in the frequency of adverse events for some comparisons.

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Executive Summary

Main Points

- ***Cervical arthroplasty versus anterior cervical discectomy and fusion (ACDF):*** The likelihood of reoperation was substantially lower at 24 months with 1-level cervical arthroplasty versus ACDF (strength of evidence [SOE]: High); 2-level cervical arthroplasty was also associated with a lower likelihood of reoperation at 24 months (SOE: Low), with similar results at longer followup times. However, rates of reoperation for ACDF at the index level may be influenced by the need to remove an existing plate to treat adjacent segment disease. There were no differences between cervical arthroplasty and ACDF in pain or function with 1-level surgery (SOE: Moderate), whereas evidence was less strong with 2-level disease (SOE: Low) across various measures and timepoints.
- ***Anterior versus posterior approach:*** Reoperation rates were similar in patients with radiculopathy and 1-level disease (SOE: Low), but the likelihood of experiencing any serious adverse event was higher with posterior approaches than ACDF in patients with 3 or more level disease (SOE: Low).
- ***Standalone cage versus plate and cage in ACDF:*** Fusion rates were similar between the two approaches (SOE: Moderate); postoperative arm pain, function, quality of life, and adjacent level ossification were also similar (SOE: Low). Few reoperations were reported.
- ***Laminoplasty versus laminectomy and fusion:*** Postoperative neurologic function (SOE: Moderate) and general function (SOE: Low) were similar between the two approaches (SOE: Low), but the risk of experiencing a complication was lower with laminoplasty (SOE: Low), with no difference in reoperation rates (SOE: Moderate).
- ***Other comparisons:*** Evidence for other comparisons was limited. No studies meeting inclusion criteria were available to guide management of cervical degenerative disease (CDD) in asymptomatic patients with radiographic spinal cord compression or to guide management of pseudarthrosis after anterior cervical fusion.

Background and Purpose

This systematic review identifies and synthesizes research on treatments for CDD in patients with or without cervical radiculopathy or myelopathy. This topic was nominated by the Congress of Neurological Surgeons (CNS), which published prior guidelines on the management of CDD in 2009.¹⁻⁴ This review is intended to be broadly useful to clinicians and policy makers, and will also inform the development of updated guidelines from CNS or others.

Methods

This review follows standard methods for systematic reviews⁵ that are further described in the full protocol available on the Agency for Healthcare Research and Quality website: <https://effectivehealthcare.ahrq.gov/products/cervical-degenerative-disease/protocol>. The protocol was registered with PROSPERO (CRD42023386838). Searches were conducted in Ovid MEDLINE[®], CINAHL[®], Embase[®], and Cochrane CENTRAL databases from 2006 for operative treatment and 1980 for nonoperative treatment to February 15, 2023.

Investigators developed pre-established eligibility criteria in accordance with established methods⁵ and revised the criteria with input from a technical expert panel and federal partners. Methods are discussed in more detail in the full report.

Results

A total of 4,705 references from electronic database searches and reference lists were reviewed. Across all Key Questions, 114 studies in 140 publications were included. The largest number of studies evaluated the effectiveness of cervical arthroplasty compared with ACDF in patients with cervical spondylotic radiculopathy or myelopathy at one or two levels (the Key Question that compared arthroplasty with ACDF, k=36). Main findings are summarized by Key Question in Table A. Results are discussed in more detail in the full report.

Table A. Summary of findings: cervical degenerative disease treatment

Key Question	Comparison	Fusion; Effect (SOE)	Pain; Effect (SOE)	Function; Effect (SOE)	Quality of Life; Effect (SOE)	Adverse Events; Effect (SOE)
KQ 1. Radiographic spinal cord compression, no myelopathy	Surgery vs. nonoperative treatment	No evidence	No evidence	No evidence	No evidence	No evidence
KQ 2. Radiographic spinal cord compression, mild to severe myelopathy	Surgery vs. nonoperative treatment	No evidence	No evidence	Insufficient	No evidence	Insufficient
KQ 3. CDD	Surgery vs. nonoperative treatment	No evidence	Insufficient	Insufficient	No evidence	No evidence
KQ 4. CDD	ACDF vs. ACDF + collar	Insufficient	Insufficient	Insufficient	No evidence	No evidence
	ACDF vs. ACDF + EMS	Small, favors ACDF + EMS (+)	Insufficient	Insufficient	No evidence	No evidence
	Laminoplasty vs. Laminoplasty + collar	NA	Similar (+)	Similar (+)	No evidence	No evidence
	Laminoplasty vs. laminoplasty + exercise	NA	Insufficient	No evidence	No evidence	No evidence
KQ 5. Cervical radiculopathy	Anterior vs. posterior surgery	Insufficient	<u>Neck and Arm pain:</u> Similar (+)	Similar (+)	Similar (+)	<u>Reoperation:</u> Similar (+)

Key Question	Comparison	Fusion; Effect (SOE)	Pain; Effect (SOE)	Function; Effect (SOE)	Quality of Life; Effect (SOE)	Adverse Events; Effect (SOE)
KQ 6. CDD with ≥3 level disease	Anterior vs. posterior surgery	Insufficient	<u>Neck pain:</u> Similar (+) <u>Arm pain:</u> Insufficient	Similar (+)	Insufficient	<u>Mortality, severe dysphagia:</u> Similar (+) <u>Reoperation</u> Insufficient <u>SAE:</u> Moderate to Large, favors anterior (+)
KQ 7. Cervical myelopathy	Laminectomy and fusion vs. Laminoplasty	NA	Insufficient	Similar (++)	No evidence	<u>Reoperation:</u> Similar (++) <u>AEs:</u> Moderate to Large, favors laminoplasty (+)
KQ 8. CDD	Cervical arthroplasty vs. ACDF	NA	Similar (++)	Similar (++)	No evidence	<u>Reoperation:</u> Large, favors cervical arthroplasty: 1-level: (+++) 2-level: (+) <u>SAE:</u> Small, favors cervical arthroplasty (+) <u>Neurological events:</u> Similar 1-level: (+) 2-level: Insufficient
KQ9. ACDF	Standalone cage vs. plate and cage	Similar (++)	<u>Neck pain:</u> Similar (+) <u>Arm pain:</u> Insufficient	Similar (+)	Similar (+)	<u>Adjacent level ossification:</u> Similar (+)
	Titanium/titanium-coated vs. PEEK cage	Small, favoring PEEK (+)	Insufficient	Small, favoring PEEK (+)	No evidence	Insufficient
	Autograft vs. allograft vs. other osteogenic materials	Insufficient	Insufficient	Insufficient	Insufficient	<u>AEs:</u> Large, favors nonuse of BMP-2 (+)
KQ 10. Pseudarthrosis prior anterior fusion surgery	Posterior approach vs. revision anterior arthrodesis	No evidence	No evidence	No evidence	No evidence	No evidence

Key Question	Comparison	Fusion; Effect (SOE)	Pain; Effect (SOE)	Function; Effect (SOE)	Quality of Life; Effect (SOE)	Adverse Events; Effect (SOE)
KQ 11. Myelopathy, prognostic utility of MRI	T2-weighted increased signal intensity and intensity ratio, sharp signal intensity	No evidence	No evidence	No evidence	No evidence	<u>Neurologic recovery:</u> favors no signal, less sharp signal, increased signal intensity ratio (+)
	Segmental abnormalities, diffusion tensor tactography, diffusion-based spectrum imaging, radionomic- based extra tree model	No evidence	No evidence	No evidence	No evidence	<u>Neurologic recovery:</u> Insufficient
KQ 12. Imaging to detect pseudarthrosis	Dynamic radiographs (asymptomatic)	Predicts pseudarthrosis (+)	NA	NA	NA	NA
	Dynamic radiographs (symptomatic)	Predicts pseudarthrosis (+)	NA	NA	NA	NA
	Angular measurement in dynamic radiographs (population NR)	Insufficient	NA	NA	NA	NA
KQ 13. CDD and ACDF	IONM vs. no IONM	NA	No evidence	No evidence	No evidence	<u>Neurologic complications:</u> Similar (+)

ACDF = anterior cervical discectomy and fusion; AE = adverse event; BMP-2 = bone morphogenetic protein 2; CDD = cervical degenerative disease; EMS = electromagnetic stimulation; IONM = intraoperative neuromonitoring; KQ = Key Question; MRI = magnetic resonance imaging; NA = not applicable; NR = not reported; PEEK = polyetheretherketone; SAE = serious adverse event; SOE = strength of evidence; T2 = T2 weighted image
Strength of Evidence: low (+), moderate (++), high (+++)

Conclusions

There were few differences in benefits between surgical approaches, devices, and techniques for the treatment of CDD. However, there were some differences in the frequency of adverse events for some comparisons. Reoperation rates were lower with artificial disc replacement than ACDF; however, indication for reoperation was not consistently described and the potential impact on re-operation at index level for plate removal to treat adjacent segment disease is unknown. Limited evidence also suggests a lower likelihood of experiencing any serious adverse event with ACDF than posterior cervical disc fusion, and a lower risk for any complication with laminoplasty compared with laminectomy and fusion. There was limited or no evidence for other comparisons.

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1. Introduction

1.1 Background

The cervical spine is comprised of seven vertebrae with discs between the vertebrae that are comprised mostly of water. Cervical degenerative disease (CDD) refers to a cascade of events that leads to changes of the vertebral discs resulting in disc desiccation and height loss. These changes may cause uncovertebral and facet joint hypertrophy (enlargement of vertebral joints) leading to vertebral foraminal narrowing (stenosis), which may cause radiculopathy (pain, motor and sensory deficits) as the exiting nerve roots are pinched, or more central stenosis with compression of the spinal cord and associated myelopathy (sensory and motor deficits and pain or myelopathy may be asymptomatic). While both conditions can affect the neck and upper extremities, cervical spondylotic myelopathy can also cause poor proprioception and spasticity of the lower extremities resulting in gait disturbances, as well as disturbances in bladder function caused by compression of motor and sensory neurologic pathways travelling through the cervical cord. Cervical radiculopathy and cervical spondylotic myelopathy may exist simultaneously.

Although the etiology of CDD is not fully understood, it is a common condition that becomes more prevalent with age. The estimated prevalence of any spinal degenerative disease from 2005 to 2017, in people 65 and older, based on Medicare data of approximately 1.7 million individuals, is 27.3 percent, with the highest prevalence for degenerative disc disease (12.2%).¹ In a separate Medicare database study, 3,156,215 individuals were identified with degenerative cervical disease (incidence 18.9% for females, 13.1% for males between 2006 and 2012).² However, the presence of CDD may not correlate well with symptoms.³ For example, one systematic review⁴ found the prevalence of multilevel degenerative disc pathology to be 64.5 percent in asymptomatic subjects (compared with 89.7% in a symptomatic population).

1.2 Management of Cervical Degenerative Disease

Of the over 3 million individuals with CDD in the Medicare study mentioned above, 32 percent were treated nonoperatively and 7 percent were treated with spinal fusion (permanently joining two or more vertebrae) within a year of diagnosis.² Surgical treatment for cervical radiculopathy varies and includes both anterior and posterior based procedures. When approached anteriorly, intervertebral spacers and additional plating may be used, the vertebrae may or may not be fused, and the cervical disc(s) may or may not be replaced.⁵ In addition to anterior cervical discectomy with fusion, cervical disc replacement and anterior cervical corpectomy (removal of the vertebral body) with fusion, surgical treatment for cervical spondylotic myelopathy also includes posterior procedures: laminoplasty (surgery to enlarge spinal canal by cutting the bony roof [lamina] and allowing it to open like a door), laminectomy (surgery that enlarges spinal canal by removing a portion of the lamina), and laminectomy with fusion.⁶ Nonoperative treatment of CDD includes analgesics, corticosteroids, neck immobilization, traction of the cervical spine, interventional approaches (e.g., radiofrequency ablation [a procedure that destroys nerve tissue that sends pain signals to the brain using radiowaves]), physical therapy, exercises, thermal therapy, and avoidance of provocative activities.^{7,8} The goals of both surgical and nonoperative treatments are to alleviate pain, improve neurologic function, and prevent progression or recurrence.

1. Introduction

While cervical myelopathy and radiculopathy are clinical diagnoses, magnetic resonance imaging (MRI) is used to confirm levels where compression of the spinal cord or nerve roots is evident. Various degenerative features can be seen on cervical MRI such as decreased vertebral height, disc height loss, osteophyte formation, disc bulging and location, hypertrophy and ossification of the posterior longitudinal ligament, spinal cord compression and flattening, and tethering (attachment) of the spinal cord to the spinal canal.⁹ MRI findings can then help guide treatment. It is important to note that the presence of degenerative findings on MRI does not equate to symptomatic consequence. One study found that 28 percent of asymptomatic volunteers over the age of 40 years (N=23, levels=97) demonstrated cervical degenerative changes on MRI (versus 14% in those less than 40 years of age).¹⁰ Intraoperative neuromonitoring (e.g., somatosensory, motor evoked potential measurements, spontaneous and triggered electromyography) is used during cervical spine surgery to provide intraoperative assessments of neural function and detect neurological injury during surgery to potentially mitigate or prevent further injury.

1.3 Purpose and Scope of the Review

This systematic review identifies and synthesizes research on treatments for CDD in patients with cervical radiculopathy and/or myelopathy. This topic was nominated by the Congress of Neurological Surgeons (CNS), which published prior guidelines on the management of CDD in 2009.¹¹⁻¹⁴ This review is intended to be broadly useful to clinicians and policy makers, and will also inform the development of updated guidelines from CNS or others. This review also includes nonoperative management of CDD as compared with operative management, which was not part of the previous CNS guidelines.

2. Methods

2.1 Systematic Review Design Process

This Comparative Effectiveness Review follows methods of the Agency for Healthcare Research and Quality (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews (hereafter the “AHRQ Methods Guide”).¹⁵ All methods were determined a priori and a protocol was developed through a process that included collaboration with a Technical Expert Panel, federal partners, and public input on Key Questions and study eligibility criteria. The protocol was registered on the PROSPERO systematic reviews registry (CRD42023386838) and published on the AHRQ website:

<https://effectivehealthcare.ahrq.gov/products/cervical-degenerative-disease/protocol>.

2.1.1 Key Questions

The review is defined by 13 Key Questions that address the effectiveness and harms of treatments for cervical degenerative disease (CDD), as well as how effectiveness and harms may differ by patient and disease characteristics (e.g., age, gender, severity of disease, vertebral level(s) of involvement). Two Contextual Questions were also included to help inform the report. Contextual Questions are not reviewed using systematic review methodology. The Key Questions, Contextual Questions, and analytic framework (Figure 1) are below.

Key Question 1: In patients with radiographic spinal cord compression and no cervical spondylotic myelopathy, what are the comparative effectiveness and harms of surgery compared to non-operative treatment or no treatment?

Key Question 2: In patients with radiographic spinal cord compression and mild to severe myelopathy, what are the effectiveness and harms of surgery versus non-operative treatment or no treatment? How do the effectiveness and harms vary by level of severity of myelopathy at the time of surgery?

Key Question 3: In patients with cervical degenerative disease, what are the comparative effectiveness and harms of surgical compared to non-operative treatment?

Key Question 4: In patients with cervical degenerative disease, what are the comparative effectiveness and harms of therapies added on to surgery (pre- or post-operative) compared with the same surgery alone?

Key Question 5: In patients with cervical radiculopathy due to cervical degenerative disease, what are the comparative effectiveness and harms of posterior versus anterior surgery?

2. Methods

Key Question 6: In patients with cervical degenerative disease, what are the comparative effectiveness and harms of posterior versus anterior surgery in patients with greater than or equal to three level disease?

Key Question 7: In patients with cervical spondylotic myelopathy due to cervical degenerative disease, what are the comparative effectiveness and harms of cervical laminectomy and fusion compared to cervical laminoplasty in patients?

Key Question 8: In patients with cervical spondylotic radiculopathy or myelopathy at one or two levels, what are the comparative effectiveness and harms of cervical arthroplasty compared to anterior cervical discectomy and fusion?

Key Question 9: In patients undergoing anterior cervical discectomy and fusion, what are the comparative effectiveness and harms of surgery based on interbody graft material or device type?

Key Question 10: In patients with pseudarthrosis after prior anterior cervical fusion surgery, what are the comparative effectiveness and harms of posterior approaches compared to revision anterior arthrodesis?

Key Question 11: In patients with cervical spondylotic myelopathy, what is the prognostic utility of preoperative magnetic resonance imaging (MRI) findings for neurologic recovery after surgery?

Key Question 12: What are the sensitivity and specificity of imaging assessment for identifying symptomatic pseudarthrosis after prior cervical fusion surgery?

Key Question 13: In patients with cervical spondylotic myelopathy, what are the comparative effectiveness and harms of intraoperative neuromonitoring (e.g., with somatosensory or motor evoked potential measurements) versus no neuromonitoring on clinical outcomes in patients undergoing surgery?

For purposes of these Key Questions, we focused on symptomatic CDD; with the exception of Key Question 1, evaluation and management of asymptomatic disease is beyond the scope of this review.

2. Methods

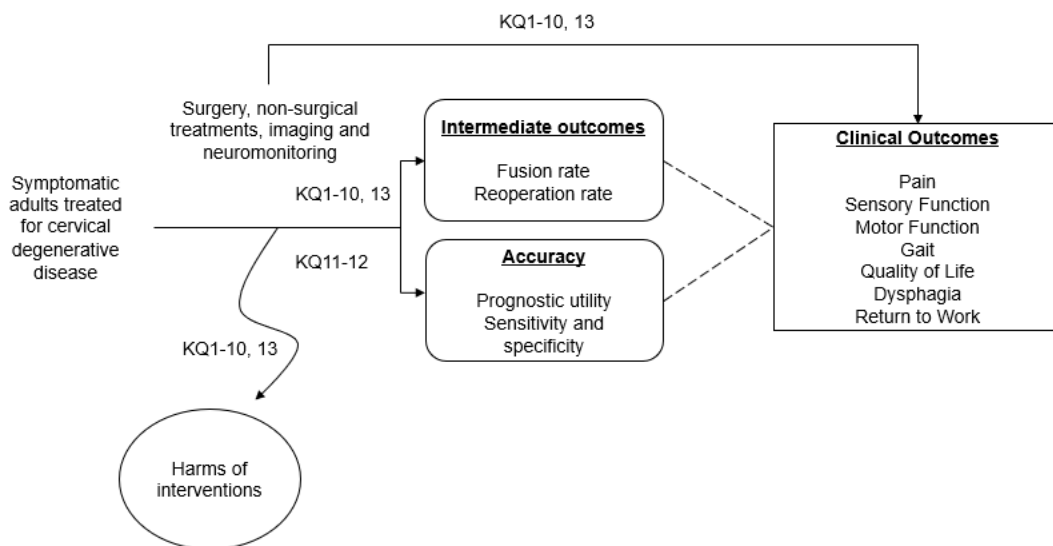
2.1.2 Contextual Questions

Contextual Question 1: What is the prevalence of cervical degenerative disease with spinal cord compression in asymptomatic patients?

Contextual Question 2: What is the natural history of untreated spinal cord compression in patients with cervical degenerative disease?

2.1.3 Analytic Framework

Figure 1. Analytic framework



KQ = Key Question

The analytic framework illustrates how the populations, interventions, and outcomes relate to the Key Questions in the review.

2.2 Study Selection

2.2.1 Literature Search Strategy

We conducted electronic searches in Ovid MEDLINE[®], Embase[®], and Cochrane CENTRAL from 1980 to February 15, 2023 (see Appendix A1.1 for full strategies). For Key Questions that compare operative approaches, we searched databases for studies published after 2006 (studies published in 2007 or earlier were included in the 2009 guidelines).¹³ Additionally, we reviewed all studies included in the 2009 guidelines for inclusion in this review.¹³ For Key Questions not covered by the 2009 guidelines (e.g., operative versus nonoperative studies, neuromonitoring studies) we searched the databases from 1980 to the present in order to identify relevant, earlier studies based on when technologies such as neuromonitoring and advanced imaging were first used in research trials. Reference lists of included systematic reviews were screened for additional studies and relevant references were carried forward. A Federal Register notification for a Supplemental Evidence and Data for Systematic review portal was posted from August 12th

2. Methods

to September 12th, 2022, for submission of unpublished studies. The search strategy was peer-reviewed by another medical librarian.

2.2.2 Inclusion and Exclusion

Criteria were established *a priori* to determine eligibility for inclusion and exclusion of abstracts in accordance with the AHRQ Methods Guide.¹⁵ The criteria for inclusion and exclusion of studies for this systematic review are based on the Key Questions and are described in Table 1 (see Appendix A for complete details, and Appendix B for all included studies). More information on data management methods can be found in Appendix A2.1. For studies meeting inclusion criteria, evidence tables were constructed, with results relevant to each Key Question abstracted in Appendix C and Risk of Bias ratings in Appendix D. Excluded studies and their exclusion codes are included in Appendix E.

Table 1. PICOTS – inclusion and exclusion criteria

PICOTS	Include	Exclude
Population	<ul style="list-style-type: none"> Age 18 and above with symptomatic cervical degenerative disease (e.g., pain, radiculopathy, myelopathy) for all KQs except for KQ1, which includes asymptomatic patients Effectiveness and harms of surgery based on patient characteristics, disease characteristics and radiographic characteristics (e.g., age, gender, comorbidities [e.g., comorbid lumbar disease, autoimmune disease, neurological disease, mental illness, Down's syndrome], severity of cervical degenerative disease, Frailty Index, sagittal vertical aspect, degree of kyphosis, prior treatment [e.g., bracing, traction, medications, massage, acupuncture, injections, chiropractic care, spinal manipulation], duration of pain, skill of surgeon) 	<ul style="list-style-type: none"> Younger than 18 years Patients without cervical degenerative disease Nonhumans
Interventions	<ul style="list-style-type: none"> Cervical spine surgery (e.g., discectomy, disc replacement, fusion up to T2, cervical arthroplasty, laminectomy, laminoplasty, corpectomy, cervical hybrid surgery, foraminotomy, ACDF cage vs. ACDF cage + plate) Non-surgical treatments (e.g., heat, exercise, acupuncture, drugs, radiofrequency ablation, steroid injections, Botox® for neck pain, psychological strategies [e.g., cognitive behavioral therapy], occupational therapy, multidisciplinary rehabilitation) Intraoperative neuromonitoring Imaging to identify symptomatic pseudarthrosis after cervical fusion surgery Preoperative MRI to predict neurologic recovery in myelopathy 	<ul style="list-style-type: none"> Preoperative imaging using CT or plain films KQ4: intraoperative therapy KQ7: laminectomy without fusion
Comparators	<ul style="list-style-type: none"> Any included intervention Placebo, waitlist, active control No comparator (KQs 11 and 12) 	<ul style="list-style-type: none"> Nonoperative intervention versus nonoperative intervention without surgical comparator

2. Methods

PICOTS	Include	Exclude
Outcomes	<ul style="list-style-type: none"> Pain, sensory function, motor function, gait, quality of life (e.g., VAS, NRS, NDI, SF-36, SF-12, EQ-5Dm, mJOA score, Nurick score, MDI, PROMIS-29), dysphagia scales, return to work Fusion rate, reoperation rate Harms (e.g., withdrawals due to adverse events, serious adverse events, new symptomatic adjacent segment disease, postoperative infection, device failure, ossification of the posterior ligament, development of kyphotic deformity) Sensitivity and specificity of imaging after cervical fusion surgery 	<ul style="list-style-type: none"> Nonvalidated instruments
Timing	<ul style="list-style-type: none"> All time periods 	None
Setting	<ul style="list-style-type: none"> Inpatient, outpatient, ambulatory surgical centers 	None
Study types and designs	<ul style="list-style-type: none"> RCTs, prospective trials and retrospective observational studies with a control group (study N≥50), current systematic reviews KQs 11-12 and studies focused on harms as a primary outcome: large intervention series (N≥50; can be single arm, but everyone received the same intervention) 	<ul style="list-style-type: none"> KQ1-10: pre-post single-arm studies, case series (everyone selected based on outcome), case reports, systematic reviews published prior to 2007 KQ11-12: pre-post non-intervention studies, case series, case reports, systematic reviews published prior to 2007
Language	<ul style="list-style-type: none"> English language 	<ul style="list-style-type: none"> Non-English

ACDF = anterior cervical discectomy and fusion; CT = computed tomography; EQ-5Dm = EuroQol-5 dimension instrument; KQ = Key Question; MDI = myelopathy disability index; MRI = magnetic resonance imaging; mJOA = modified Japanese orthopedic association scale; NDI = Neck Disability Index; N(P)RS = numerical pain rating scale; PROMIS-29 = patient reported outcome measurement information system; RCT = randomized controlled trial; QOL = quality of life; SF-12 = 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey; VAS = visual analogue scale

We limited our review to adults with CDD who were treated with surgical interventions; comparison groups were limited to other surgical interventions with or without nonsurgical interventions (e.g., physical therapy, neck collar), nonoperative treatment alone or no treatment. Only studies with a relevant comparison group were included in this review. Single-arm studies were not included due to increased risk of bias and lack of comparative data. Primary effectiveness outcomes fell into five general categories: fusion, pain, neurologic function, general function, and quality of life. Nonexhaustive examples of neurological function outcomes included the modified Japanese Orthopedic Association scale (mJOA) and the Nurick Classification Scale; outcomes classified as general function included the Neck Disability Index (NDI), Odom's criteria, and the 36-Item Short Form Health Survey (SF-36); outcomes classified as pertaining to quality of life included the Euro Quality of Life-5 Dimension scale, the Veteran's RAND 12-Item Health Survey, and the Swallowing Quality of Life scale. Other prioritized outcomes included rates of serious adverse events, study discontinuation due to adverse events and specific adverse events (e.g., need for reoperation, neurologic deficits).

2. Methods

2.3 Risk of Bias Assessment of Individual Studies

Predefined criteria were used to assess the risk of bias (also referred to as quality or internal validity) for each individual included study, using criteria appropriate for the study design based on the AHRQ Methods guide,¹⁵ the Cochrane Back and Neck Group,¹⁶ and the U.S. Preventive Services Task Force¹⁷ (Appendix D1.1). Each study was independently reviewed for risk of bias by two team members. Any disagreements were resolved through consensus. Based on the risk of bias assessment, included studies were rated as having “low,” “moderate,” or “high” risk of bias (Appendix D1.1). Studies rated high risk of bias were not excluded a priori, but were considered to be less reliable than low or moderate risk of bias studies when synthesizing the evidence. See Appendix D1.1 for additional details.

Because most studies were rated moderate risk of bias, we call out in the text studies rated high risk of bias as extra caution should be exercised when drawing conclusions from such studies.

2.4 Data Analysis and Synthesis

Evidence tables identify study characteristics, results of interest, and risk of bias ratings for all included studies and summary tables highlight the main findings. Studies were reviewed and highlighted using a hierarchy-of-evidence approach, where the best evidence is the focus of the synthesis for each Key Question. Since the Key Questions varied in nature and scope, the approach to synthesis also varied. We analyzed the evidence according to Key Question, using both qualitative (narrative) and where possible quantitative (meta-analysis) methods. Randomized controlled trials were prioritized and studies with lower risk of bias ratings were given more consideration in our synthesis for each clinical indication and outcome.

Meta-analyses were conducted to obtain more precise effect estimates for comparative effectiveness of various interventions for cervical spine; analyses of randomized and nonrandomized evidence were conducted separately. A random effects model based on the profile likelihood method¹⁸ was used to obtain pooled risk ratio and mean difference. Statistical heterogeneity among the studies was assessed using Cochran’s χ^2 test and the I^2 statistic.¹⁹ For analyses with at least 10 trials, we constructed funnel plots and performed the Egger test to detect small sample effects (a marker for potential publication bias).²⁰ All meta-analyses were conducted using Stata/SE 16.1 (StataCorp, College Station, TX). See Appendix A2.1 for additional details on data synthesis and analysis, and Appendix F for additional forest plots.

To help determine the degree of effect, we examined the magnitude of relative risks and mean differences according to Table 2. There were instances where a statistically significant difference between treatments was of such a small magnitude as to not be clinically meaningful. Conversely, there were instances where a small, moderate, or large effect was found but was not statistically significant.

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Table 2. Definition of effect sizes

Effect Size	Definition
Small effect	MD 0.5 to 1.0 points on a 0 to 10-point scale, 5 to 10 points on a 0 to 100-point scale SMD 0.2 to 0.5 RR/OR 1.2 to 1.4
Moderate effect	MD >1 to 2 points on a 0 to 10-point scale, >10 to 20 points on a 0 to 100-point scale SMD >0.5 to 0.8 RR/OR 1.5 to 1.9
Large effect	MD >2 points on a 0 to 10-point scale, >20 points on a 0 to 100-point scale SMD >0.8 RR/OR ≥ 2.0

MD = mean difference; OR = odds ratio; RR = relative risk; SMD = standardized mean difference

Table 2 taken from the Cervical Degenerative Disease Protocol, published online at

<https://effectivehealthcare.ahrq.gov/sites/default/files/product/pdf/cervical-degenerative-protocol.pdf>

2.5 Grading the Strength of the Body of Evidence

The strength of evidence (SOE) for each body of evidence was assessed as high, moderate, low, or insufficient, using the approach described in the AHRQ Methods Guide,¹⁵ based on study limitations, consistency, directness, precision, and reporting bias. These criteria were applied regardless of whether evidence was synthesized quantitatively or qualitatively. Strength of evidence ratings reflected our confidence or certainty in the findings. Strength of evidence was considered insufficient when evidence was lacking, sparse, or too conflicting such that we were unable to draw conclusions. SOE was initially assessed by one researcher and confirmed by a second. SOE was not conducted for composite outcomes. Descriptions of criteria and overall grades are described in full in Appendix A and G.

2.6 Peer Review and Public Commentary

An associate editor from a different Evidence-based Practice Center reviewed the draft report. Experts were invited to provide external peer review of this systematic review; AHRQ also provided comments. In addition, the draft report was posted on the AHRQ website June 9 to July 7, 2023 for public comment. All comments were reviewed and used to inform revisions to the draft report. AHRQ will post a disposition of comments table 3 months after publication of the final report.

3. Results

3.1 Description of Included Studies

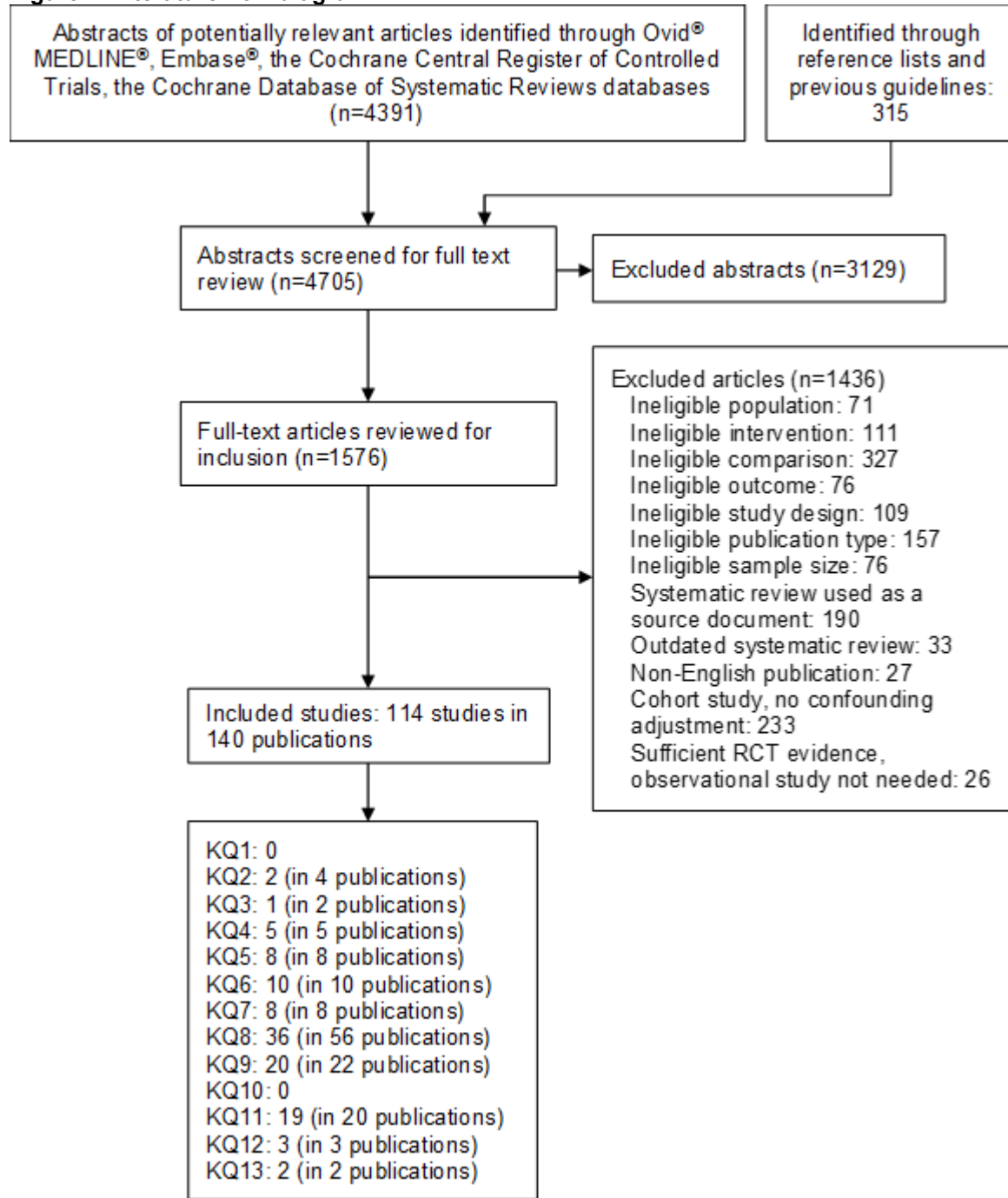
A total of 4,705 references from electronic database searches and reference lists were reviewed. After dual review of titles and abstracts, 1,576 papers were selected for full-text review, of which 1,436 articles were excluded. Of the 114 studies in 140 publications included across all Key Questions, 57 (in 82 publications) were randomized controlled trials (RCTs), 56 (in 57 publications) were observational studies, and one was a systematic review (Figure 2). Results are arranged by Key Question, then by outcome, and are summarized below, followed by tables in the accompanying text.

A list of excluded studies with reason for exclusion are in Appendix E. Data abstraction of study characteristics and results, quality assessment for all included studies, and details for grading strength of evidence (SOE) are available in Appendixes C, D, and G, respectively, while Appendix H includes all appendix references.

Most studies were rated moderate risk of bias. For these studies we do not call their risk of bias in the text. Instead we call out studies that were rated high risk of bias as additional caution should be exercised when interpreting study results.

3.1 Results, Description of Included Studies

Figure 2. Literature flow diagram



KQ = Key Question, RCT = randomized controlled trial.

57 (in 82 publications) were randomized controlled trials (RCTs), 56 (in 57 publications) were observational studies, and one was a systematic review.

Note: In the excluded articles list, when sufficient RCT evidence existed, eligible observational studies were excluded, as their level of evidence (risk of bias) would have been lower than the RCTs.

3.2 Results, Key Question 1

3.2 Key Question 1: In patients with radiographic spinal cord compression and no cervical spondylotic myelopathy, what are the comparative effectiveness and harms of surgery compared to non-operative treatment or no treatment?

No studies met eligibility criteria for Key Question 1.

3.3 Results, Key Question 2

3.3 Key Question 2: In patients with radiographic spinal cord compression and mild to severe myelopathy, what are the effectiveness and harms of surgery versus non-operative treatment or no treatment? How do the effectiveness and harms vary by level of severity of myelopathy at the time of surgery?

3.3.1 Key Findings

- Evidence from one small RCT and one small nonrandomized study of interventions (NRSI) was inadequate to determine the benefits and harms of surgery versus conservative treatment for cervical myelopathy (SOE: Insufficient).

3.3.2 Description of Included Studies

One RCT (N=68) described in three publications²¹⁻²³ and one NRSI (N=80)²⁴ compared surgery versus conservative treatment for cervical myelopathy (Appendix C). The duration of followup in the RCT was 3 years^{21,22} and 10 years.²³ The duration of followup in the NRSI was 3 years.²⁴ In the NRSI, patients were stratified by degree of myelopathy (mild and moderate versus severe) in both the surgery and conservative treatment groups. In the RCT, all patients had slowly or nonprogressing mild to moderate myelopathy. The RCT was conducted in the Czech Republic and received government funding; the NRSI was conducted in Italy and did not report funding.

The mean age of participants was 53 years with 29 percent females in the RCT and 66 years with 44 percent female in the NRSI. The duration of disease was 2 years (range 0.3 to 12 years) in the RCT and the mean duration of symptoms was 25 months (range 3 to 57 months) in the NRSI.

Surgery consisted of anterior decompression (N=22) with bone graft (N=20), corpectomy (N=6), and laminoplasty (N=5) in the RCT. An anterior approach was used in 1- or 2-level cord compression and a posterior approach was used in multilevel spinal stenosis. Surgery consisted of microsurgical anterior corpectomy, discectomy, use of titanium mesh and anterior plating in the NRSI. For 3- or multi-level corpectomy, posterior stabilization was also performed. Surgical patients wore a cervical collar for 4 weeks postoperatively. In the RCT, conservative treatment consisted of cervical collar, anti-inflammatory medication, and bed rest. However, surgical patients also received these treatments. Conservative treatment in the NRSI was similar to treatments in the RCT, but also included physiotherapy.

The RCT was rated moderate risk of bias due to lack of blinding and unclear randomization methods (Appendix D). The NRSI was rated high risk of bias due to unclear differences in patient baseline characteristics across groups and potential selection bias in treatment given (Appendix D). The strength of evidence for neurologic and general function was rated insufficient due to conflicting evidence from two small studies (Appendix G).

3.3.3 Detailed Analysis

3.3.3.1 Fusion

No studies reported fusion outcomes.

3.3 Results, Key Question 2

3.3.3.2 Pain

No studies reported pain outcomes.

3.3.3.3 Neurologic Function

Evidence from one small RCT and one small NRSI was inadequate to determine the benefits and harms of surgery versus conservative treatment on neurologic function in patients with cervical myelopathy (SOE: Insufficient).

In the RCT, patients were considered to be responders if Modified Japanese Orthopaedic Association Scale (mJOA) scores (maximum 18 points) were improved or unchanged following treatment.²² The likelihood of mJOA response was slightly less with surgery compared with conservative therapy at 6 months (N=66, 61% vs. 73%, relative risk [RR] 0.83, 95% confidence interval (CI) 0.59 to 1.18) and at 36 months (N=59, 59% vs. 73%, RR 0.80, 95% CI 0.55 to 1.16), although differences were not statistically significant. However, mean mJOA scores were not different between surgery and conservative treatment at 6, 12, 24, and 36 months after controlling for baseline values. Ten-year followup of the RCT (N=47) also found no differences between treatment groups on the mJOA (14 vs. 15, p=0.114).²³

In the NRSI, patients were divided into four groups (N=20 patients per group) and followed for 3 years: patients with mild to moderate myelopathy treated with surgery; patients with mild to moderate myelopathy treated conservatively; patients with severe myelopathy treated with surgery; patients with severe myelopathy treated conservatively.²⁴ Mild to moderate myelopathy was defined as a mJOA score of 12 and above, severe myelopathy as a score below 12. Patients with severe myelopathy experienced a longer duration of symptoms (40 months) than patients with mild to moderate disease (10 months) and were more likely to receive multilevel surgery than surgical patients with mild to moderate disease. Mean mJOA scores improved over time for both surgery and conservative treatment but favored surgery at 12 and 36 months in patients with mild to moderate myelopathy (12 months mJOA: 15.4 vs. 14.2, p=0.03; 36 months: 16.1 vs. 15.2, p=0.013). In patients with severe myelopathy improvement in mJOA scores was greater with surgery compared with conservative treatment beginning at 6 months (6 months mJOA: 9.5 vs. 7.9, p=0.045; 12 months: 11.5 vs. 8.6, p=0.001; 36 months: 12.45 vs. 8.65, p<0.001).

3.3.3.4 General Function

Evidence from one small RCT and one small NRSI was inadequate to determine the benefits and harms of surgery versus conservative treatment on general function in patients with cervical myelopathy (SOE: Insufficient).

The time required to complete the 10-meter Walk Test in the RCT (N=66) increased over time through 24 months in patients treated with surgery (baseline: 7.9 seconds; 6 months: 8.7 sec; 12 months: 9.9 sec; 24 months: 11.7 sec; 36 months: 9.4 sec), whereas there was little change in time needed to complete the 10-meter walk throughout the followup period with conservative treatment (baseline: 7.4 sec; 6 months: 7.2 sec; 12 months: 7.4 sec; 24 and 36 months: 7.5 sec).²¹ These differences in walk time between treatments were statistically significant (p-value range 0.034 to 0.003), although the differences between groups is not likely clinically meaningful. Ten-year followup of the RCT (N=47) found no differences on the 10-meter Walk Test (7.3 seconds vs. 7.1 seconds, p=0.207).²³ There was no difference, however, in the NRSI, between treatment with surgery versus conservative therapy on the 10-meter Walk Test in patients with mild to moderate myelopathy, whereas there was greater improvement on the 10-Meter Walk Test with surgery in patients with severe myelopathy at 12 and 36 months (12

3.3 Results, Key Question 2

months: 11.4 seconds vs. 14.4 seconds, $p=0.005$; 36 months: 10.30 seconds vs. 14.10 seconds, $p=0.002$).²⁴

In the RCT, patients were videoed performing activities of daily living (ADL) such as buttoning a shirt, brushing teeth and hair, walking, going up and down stairs, and running and were evaluated by blinded observers on a 7-point improvement scale that ranged from 3 (excellent) to -3 (poor); 0 represented no change in ability.²¹ Patients treated with surgery showed a greater likelihood of improvement in ADLs compared with conservative treatment at 6 months (20% vs. 5.9%) but there was also a greater likelihood of worsening in ADLs with surgery (20% vs. 8.8%) at 6 months. There were no differences between treatments in changes in ADL abilities at 12, 24, or 36 months. Video evaluation of decreased ability to perform ADLs was also not different between treatment groups at 10 years (mean of two evaluators: 56.8% vs. 50%, $p>0.05$).²³ However, with the limited sample size available, this 10-year followup was likely underpowered to demonstrate a difference between surgery and conservative treatment.

Although more patients in the RCT reported that their disease course had improved after surgery compared with conservative therapy at 6 months posttreatment (61% vs. 20%, $p=0.001$), self-perception of improved diseased course deteriorated over time in the surgery group ($p=0.019$ for negative trend) and was 20 percent at 36 months compared with a relatively stable course with conservative treatment.²¹ Ten-year followup of the RCT ($N=47$) found no difference between treatment groups on a subjective evaluation of worsened status (45.5% vs. 56%, $p=0.47$).²³

The physical component summary score (PCS) and the mental component summary score (MCS) on the 12-Item Short Form Health Survey (SF-12) were not different posttreatment (unclear posttreatment time) in patients with mild to moderate myelopathy who received surgery compared with patients who received conservative therapy (PCS: 37.4 vs. 37.95, $p=0.75$; MCS: 47.5 vs. 46.7, $p=0.78$).²⁴ However, improvement in scores was greater with surgery versus conservative treatment in patients with severe myelopathy (PCS: 53.3 vs. 26.85, $p<0.001$; MCS: 61.2 vs. 31.4, $p<0.001$).

3.3.3.5 Quality of Life

No studies reported quality of life outcomes.

3.3.3.6 Harms

The NRSI reported that two patients with severe myelopathy who received conservative treatment demonstrated progressive neurological worsening (defined as a worsening of 1 point on the mJOA).²⁴ Surgical complications in this study included 5/40 patients (12.5%) who experienced airway obstruction, graft displacement, and/or wound hematoma. There were no deaths.

The findings of the NRSI, particularly the findings in patients with severe myelopathy, should be interpreted with caution as the individuals in the severe myelopathy group who received conservative treatment consisted of those who refused surgery against medical advice, which may have introduced selection bias.

3.4 Results, Key Question 3

3.4 Key Question 3: In patients with cervical degenerative disease, what are the comparative effectiveness and harms of surgical compared to non-operative treatment?

3.4.1 Key Findings

- There was inadequate evidence from one small RCT on the comparative effectiveness of anterior cervical discectomy and fusion (ACDF), physiotherapy, and treatment with a cervical collar on pain and function in patients with cervico-brachial pain without spinal cord compression (SOE: Insufficient).

3.4.2 Description of Included Studies

One RCT (N=81) described in two publications^{25,26} compared treatment for cervico-brachial pain with cervical decompression and fusion, physiotherapy, or neck collar (Appendix C). All patients had nerve root compression on magnetic resonance imaging (MRI) without spinal cord compression, a history of pain for 3 or more months, and were followed for 16 months. The study was conducted in Sweden.

The mean age of participants was 47 years and 46 percent were female; race or ethnicity were not reported. The worst affected level was C5-C6 (49%) followed by C6-C7 (37%). Prior treatments included physiotherapy (85%; physiotherapy uses a hands on approach to healing, e.g., massage, fascial releases, whereas physical therapy uses hands-on methods but also incorporates physical exercises and use of a cervical collar (42%). Mean duration of pain was 34 months (range 5 to 120 months).

Surgery consisted of ACDF using the Cloward technique and fusion achieved with purified cow bone graft; one patient received a posterior laminectomy. Surgical patients sometimes wore a collar for 1 to 2 days postoperatively. Physiotherapy included traction (70%), strengthening exercises (56%), stretching exercises (56%), massage (33%), heat (33%), and transcutaneous electrical stimulation (22%), among other modalities. Patients treated with cervical collars used a rigid collar during the day and an optional soft collar at night for 3 months.

The trial was rated moderate risk of bias due to lack of blinding and overlap in treatments after 16 weeks (Appendix D). The strength of evidence for pain, neurologic function and general function was rated insufficient due to limited evidence from one small trial (Appendix G).

3.4.3 Detailed Analysis

3.4.3.1 Fusion

No studies reported fusion outcomes.

3.4.3.2 Pain

There was inadequate evidence from one small RCT on the comparative effectiveness of ACDF, physiotherapy and treatment with a cervical collar on pain in patients with cervico-brachial pain without spinal cord compression (SOE: Insufficient).

There were no differences between treatments in current pain or worst pain using the visual analogue scale (VAS) (0-100) at baseline.²⁵ At 14 to 16 weeks followup patients treated with surgery experienced less “current” pain than patients treated with a collar (N=54, 0-100 VAS: 27 vs. 48, $p<0.01$), but there was no difference between surgery, physiotherapy, and use of a collar

3.4 Results, Key Question 3

in “current” pain at 16 months (N=81, VAS: 30 vs. 39 vs. 35, $p>0.05$). Results were similar regarding “worst” pain with surgical patients experiencing less “worst” pain than collar patients at 14-16 weeks (N=54, VAS: 43 vs. 64, $p<0.001$) but no differences in “worst” pain between treatments at 16 months (N=81, VAS: 42 vs. 53 vs. 52, $p>0.05$, respectively).

3.4.3.3 Function

3.4.3.3.1 Neurological Function

There was inadequate evidence from one small RCT on the comparative effectiveness of ACDF, physiotherapy and treatment with a cervical collar on neurologic function in patients with cervico-brachial pain without spinal cord compression (SOE: Insufficient).

Specific muscle strength before and after treatment was also assessed.²⁶ Patients in the surgery group experienced greater improvements in muscle strength (strength expressed as the ratio of the affected to the unaffected side) at 14 to 16 weeks in pinch grip, elbow extension and shoulder internal rotation compared with patients treated with physiotherapy and greater improvements in wrist flexion and elbow flexion compared to those treated with a cervical collar (data not provided). At 16 months, patients treated with surgery experienced greater improvements in wrist extension, elbow extension, shoulder abduction, and shoulder internal rotation compared with patients treated with physiotherapy. There were no differences in strength improvement between surgery and collar treatment or between physiotherapy and collar treatment at 16 months (data not provided).

At 14 to 16 weeks posttreatment, there was no difference in the likelihood of improvement in paresthesias with surgery compared with physiotherapy or collar treatment (N=81, 52% vs. 45% vs. 37%, $p>0.05$) but a large increase in the likelihood of improvement in sensory loss with surgery compared with either treatment (41% vs. 15%, RR 2.75, 95% CI 1.0 to 7.5, both comparisons with surgery).²⁶ At 16 months, there remained no difference between treatment in the likelihood of improvement in paresthesias between surgery, physiotherapy, and treatment with a collar (N=81, 58% vs. 67% vs. 66%, $p>0.05$). There was also no difference between treatments in the likelihood of improvement in sensory loss at 16 months (N=81, 27% vs. 14% vs. 15%, $p>0.05$).

3.4.3.3.2 General Function

There was inadequate evidence from one small RCT on the comparative effectiveness of ACDF, physiotherapy and treatment with a cervical collar on general function in patients with cervico-brachial pain without spinal cord compression (SOE: Insufficient).

The ability to complete basic activities of daily life (e.g., dressing, prolonged sitting) to more rigorous physical activity (e.g., running, heavy work) was assessed using the disability rating index (DRI).²⁵ Overall mean score on the DRI ranges from 0 to 100, with ability on each of 12 activities rated using a 0-100 VAS scale indicating “without difficulty” to “not at all.” There was no difference between treatment with surgery versus physiotherapy at 14-16 weeks on improvement in disability, however treatment with surgery resulted in improved dressing and heavy work compared with treatment with a collar, while treatment with physiotherapy was associated with greater ability to walk, sit for a long time, and complete heavy work compared with collar treatment ($p<0.05$, data not provided). At 16 months the ability to do heavy work was greater with surgery compared to the other treatments ($p<0.05$, data not provided). No other differences on the DRI were noted.

3.4 Results, Key Question 3

Although findings from this small study tended to favor surgery, especially in the short term, these findings should be interpreted with caution due to patients receiving additional treatments beyond the randomized treatment and the heterogeneity of treatment (especially physiotherapy). After 16 weeks, 8/27 surgery patients (30%) underwent a second surgery. Additionally, one patient treated with physiotherapy (4%) and five treated with collar (19%) underwent surgery. Forty-one percent of surgery patients (11/27) received physiotherapy as did 44% (12/27) of patients treated with a collar. Additionally, the use of specific physiotherapy modalities (e.g., traction, exercises, cryotherapy) varied and was at the discretion of the local physiotherapist.

3.4.3.4 Quality of Life

This study did not report quality of life outcomes.

3.4.3.5 Harms

This study did not report harms or adverse events.

3.5 Results, Key Question 4

3.5 Key Question 4: In patients with cervical degenerative disease, what are the comparative effectiveness and harms of therapies added on to surgery (pre- or post-operative) compared with the same surgery alone?

3.5.1 Key Findings

- Laminoplasty
 - There was low strength evidence of no difference in pain and function between use of a post-operative collar plus laminoplasty versus laminoplasty alone (SOE: Low).
 - There was inadequate evidence to determine the effects on pain with laminoplasty plus exercise versus laminoplasty alone (SOE: Insufficient).
- ACDF
 - There was low-strength evidence that use of post-operative pulsed electromagnetic field (PEMF) stimulation after ACDF was associated with increased fusion versus treatment with ACDF alone (SOE: Low); pain and function were similar with or without PEMF after ACDF (SOE: Low).
 - There was inadequate evidence to determine the effects on fusion, pain, and function of ACDF plus post-operative collar compared with ACDF alone (SOE: Insufficient).

3.5.2 Description of Included Studies

Five RCTs (N=546)²⁷⁻³¹ compared surgery plus post-operative therapy to surgery alone (Appendix C). The average mean followup duration was 12 months (range 1 week to 2 years). Two trials were conducted in Japan,^{30,31} and one trial each in the United States,²⁹ Sweden,²⁷ and China.²⁸

The average study mean age of participants was 59 years (range 47 to 73 years); the average proportion of females in studies was 38 percent (range 29% to 47%). Two trials reported race, one enrolling a majority of White participants (93%)²⁹ and the other enrolling Chinese participants.²⁸ Studies enrolled patients with clinical and/or radiological evidence of cervical myelopathy^{28,30,31} or radiculopathy.^{27,29} Patients had 1-2 level disease in 1 trial (N=33),²⁷ 1-4 levels (60% had 2 levels) in 1 trial (N=323),²⁹ and a mean of 4.5 levels in 1 trial (N=90).³⁰ Two trials did not report number of disease levels.^{28,31}

One trial was rated low risk of bias,^{28,29} and the remainder were rated moderate risk of bias (Appendix D). Methodological limitations included unclear blinding of providers or assessors and high loss to followup. Evidence for pain and function with laminoplasty plus exercise versus laminoplasty alone and evidence for fusion, pain and function for ACDF plus post-operative collar versus ACDF alone were rated insufficient due to limited evidence from one small trial each (Appendix G).

3.5.3 Detailed Analysis

3.5.3.1 Laminoplasty Plus Nonoperative Therapy Versus Laminoplasty

Three RCTs (N=190) assessed laminoplasty plus post-operative Philadelphia collars^{28,30} or exercise therapy incorporating 3 months of daily strengthening and range of motion exercises.³¹

3.5 Results, Key Question 4

3.5.3.1.1 Fusion

No study reported fusion outcomes.

3.5.3.1.2 Pain

There was no difference in pain between the use of a post-operative collar plus laminoplasty versus laminoplasty alone (SOE: Low). There was inadequate evidence to determine the effects on pain with laminoplasty plus exercise versus laminoplasty alone (SOE: Insufficient).

Single-door laminoplasty plus rigid Philadelphia collar worn for 3 weeks post-operatively was associated with less improvement in mean VAS scores (0-10 scale) than laminoplasty alone at weeks 1 (0.8 vs. 3.8, $p=0.023$) and 2 (-0.9 vs. 1.8, $p=0.046$) in one trial rated low risk of bias (N=35), with no difference at other timepoints (3 weeks: -1.2 vs. 1.1, $p=0.148$) or at other followup times (6 weeks and 3, 6, and 12 months).²⁸ One trial (N=90) compared modified double-door laminoplasty plus Philadelphia collar worn for 2 weeks post-operatively and found no differences in change in VAS (0-10 scale) at 12 months (-0.19 vs. -0.04, $p>0.05$) or throughout the study period ($p=0.487$).³⁰

One RCT (N=65) found no difference in mean VAS scores (0-100 scale) for neck pain and stiffness at 2 weeks and 3 months postoperative between muscle-preserving laminoplasty with exercises versus laminoplasty alone (3 months: -1.8 vs. -2.5, $p=0.623$).³¹

3.5.3.1.3 Function

3.5.3.1.3.1 Neurologic Function

There was no difference in neurologic function between the use of a post-operative collar plus laminoplasty versus laminoplasty alone (SOE: Low).

One trial of open-door laminoplasty (N=35) found no difference on mJOA scores between 3 weeks of post-operative collar versus no collar at 6 weeks (mJOA: 13.8 vs. 13.3, $p=0.613$)²⁸ or longer followup. This was consistent with 12-month results from the second collar trial (N=90) which reported no difference in end-of-study mJOA scores between 2 weeks of post-operative collar use and no collar (11.1 vs. 11.8, $p=0.22$).³⁰

3.5.3.1.3.2 General Function

There was no difference in general function between the use of a post-operative collar plus laminoplasty versus laminoplasty alone (SOE: Low). Two trials (N=125) of laminoplasty with or without the addition of a postoperative Philadelphia collar for 2 or 3 weeks were consistent in finding no difference in 36-Item Short Form Health Survey (SF-36) PCS and MCS scores with collar use compared to no collar. One RCT (N=35) of single-door laminoplasty found no differences in SF-36 scores between the use of a post-operative collar for 3 weeks versus no collar at 6 weeks after surgery when controlling for baseline scores (PCS: 6.4 vs. 2.8; MCS: 4.1 vs. 0, $p>0.05$) or at longer followup times (3, 6, 12, 24 months).²⁸ One RCT (N=90) of double-door laminoplasty plus 2 weeks of postoperative collar use versus no collar also found no difference at 12 months in change in SF-36 PCS or MCS scores (PCS: 1.5 vs. 1.4, $p>0.05$; MCS: 0.1 vs. 0.4, $p>0.05$).³⁰ The trial of open-door laminoplasty also found no difference on Neck Disability Index (NDI) between 3 weeks of post-operative collar and no collar at 6 weeks (NDI: 24.8 vs. 34.0, $p=0.147$) or at longer followup.²⁸

3.5 Results, Key Question 4

3.5.3.1.4 Quality of Life

No study reported quality of life outcomes.

3.5.3.2 ACDF Plus Nonoperative Therapy Versus ACDF

One trial (N=33) assessed ACDF versus ACDF plus rigid Philadelphia collar worn for 6 weeks postoperative²⁷ and one trial (N=323) compared ACDF with ACDF plus PEMF, delivered using a Cervical-Stim device for 4 hours daily from 1 week to 3 months postoperatively in a trial of active smokers (all patients wore a cervical collar for 1 week postoperatively).²⁹

3.5.3.2.1 Fusion

There was inadequate evidence to determine the effects on fusion between ACDF with or without collar use (SOE: Insufficient). Use of post-operative PEMF stimulation after ACDF was associated with increased fusion versus treatment with ACDF alone (SOE: Low).

All ACDF patients in one 24-month trial (N=33) achieved radiographic fusion regardless of collar use (100% vs. 100%).²⁷ Surgical details were not provided.

PEMF was associated with small increase in fusion rates at 6 months in one trial (N=323) based on a per protocol analysis versus ACDF with no PEMF (N=240; 83.6% vs. 68.6%, $p=0.0065$); fusion rates were also improved in intent-to-treat analyses assuming missing patients fused (N=323; 85.9% vs. 76.3%, $p=0.0269$) or imputing patient status at last visit (N=281; 78.2% vs. 64.8%, $p=0.0127$), but not when assuming missing patients did not fuse (65.6% vs. 56.3%, $p=0.0835$).²⁹ However, there was no difference in fusion rates in the per protocol analysis at 12 months.²⁹ This study used a Smith-Robinson technique with allograft and cervical plate system.

3.5.3.2.2 Pain

The ACDF trial of PEMF versus no PEMF found similar VAS scores for shoulder/arm pain at rest or with activity at 6 and 12 months postoperative (data provided in graph form)²⁹ (SOE: Low).

3.5.3.2.3 Function

3.5.3.2.3.1 General Function

There was inadequate evidence to determine the effect on general function of ACDF plus post-operative collar compared with ACDF alone for all time points (SOE: Insufficient).

Collar use was associated with greater improvement in SF-36 PCS scores from baseline than ACDF without a collar at 6 weeks (mean difference [MD] 5.8; 95% CI 0.8 to 10.7), 3 months (MD 6.8; 95% CI 0.4 to 13.1), 6 months (MD 7.4; 95% CI 1.4 to 13.4), and 12 months (MD 7.5; 95% CI 0.3 to 14.6), but not at 24 months (MD 4.9; 95% CI -0.8 to 10.5; $p=0.088$).²⁷ In the same trial, there was no difference in mean change in SF-36 MCS scores at 6 weeks (MD -1.9; 95% CI -11.1 to 7.4) or at longer postoperative followup times.²⁷

Six-weeks' collar use was associated with greater improvement in NDI scores from baseline than no collar at 6 weeks (MD -4.4; 95% CI -8.6 to -0.2), but not at 3 months (MD -2.1, 95% CI -8.0 to 3.8) or at other timepoints.²⁷ There was no difference in NDI scores between daily PEMF and no stimulation at 6 months (31.0 vs. 23.0, $p>0.05$) or 12 months postoperative (25.6 vs. 22.8, $p>0.05$).²⁹

3.5 Results, Key Question 4

3.5.3.2.4 Quality of Life

No study reported quality of life outcomes.

3.6 Results, Key Question 5

3.6 Key Question 5: In patients with cervical radiculopathy due to cervical degenerative disease, what are the comparative effectiveness and harms of posterior versus anterior surgery?

3.6.1 Key Findings

- There was low-strength evidence of no differences in neck and arm pain between anterior versus posterior approaches short term (3, 6 months) and intermediate term (12, 24 months) (SOE: Low).
- There was inadequate evidence to determine benefits of anterior versus posterior approaches for neck pain (immediately postoperative), fusion, or neurologic function (SOE: Insufficient).
- There was low-strength evidence of no difference between approaches on measures of general function or quality of life (SOE: Low).
- There was low-strength evidence of no difference between approaches in the likelihood of reoperation (SOE: Low).
- Neurologic deficits were reported inconsistently and various measures were used across studies, however there was low-strength evidence of no differences between approaches were reported (SOE: Low).
- One nonrandomized study reported higher 30-day mortality with ACDF versus posterior cervical foraminotomy (PCF), but there were very few deaths (SOE: Insufficient).
- No serious adverse events with either approach were reported in three RCTs; evidence on specific adverse events was limited; one RCT reported no difference in approaches for surgery-related adverse events (SOE: Insufficient).

3.6.2 Description of Included Studies

Four RCTs (N=277)³²⁻³⁵ compared anterior versus posterior approaches (Appendix C). The average mean followup duration was 27 months (range 12 to 60 months). One trial was conducted in the United States,³⁴ one in Germany,³³ one in Egypt,³² and one in the Netherlands.³⁵ All four trials were conducted at single sites. The average study mean age of participants for the trials was 45 years (range 43 to 51 years); the average proportion of females in trials was 55 percent (range 50% to 66%). No trials reported race. All four trials limited enrollment to patients with radiculopathy; two trials excluded patients with myelopathy,^{32,34} and the other two did not report myelopathy.^{33,35} Patients in all four trials had single-level disease. Two trials were rated moderate risk of bias^{34,35} and two trials were rated high risk of bias (Appendix D).^{32,33} One trial stated that no funding was received,³³ one trial reported government funding,³⁵ and two trials did not address funding.^{32,34} Primary methodologic concerns were unclear randomization and treatment allocation concealment, dissimilarity between treatment groups at baseline and lack of assessor blinding.

Four retrospective NRSIs (N=47,684), including one database study, compared anterior versus posterior procedures (Appendix C).³⁶⁻³⁹ Three NRSIs were conducted in the United States^{36,37,39} and one in the United Kingdom³⁸ Three studies³⁶⁻³⁸ drew patients from a single site and one³⁹ used an insurance administrative database (N=46,598). The average study mean age of participants was 50 years (range 48 to 53 years); the average proportion of females in studies was 44 percent (range 31% to 54%). One study reported race, enrolling a majority of White

3.6 Results, Key Question 5

participants (88%).³⁷ All four NRSIs limited enrollment to patients with radiculopathy. Patients had single-level disease in three NRSIs.^{36,38,39} A mean of 2.6 surgical levels was reported in one study.³⁷ Funding was not reported in two NRSIs,^{36,38} one was government funded³⁹ and one stated that no funding was received.³⁷ Three NRSIs were rated moderate risk of bias³⁷⁻³⁹ and one was rated high risk of bias (Appendix D).³⁶ Common methodologic limitations were unclear loss to followup and lack of clarity regarding assessor blinding. Additionally, lack of clarity regarding patient enrollment and comparability of treatment groups at baseline combined with inadequate adjustment for confounding for prognostic variables were concerns resulting in the NRSI being rated high risk of bias.

For many outcomes, authors did not provide adequate data to calculate effect sizes and confidence intervals. Although NRSI may have adjusted for some outcomes, authors did not always provide adjusted estimates for our outcomes of interest. Given the potential for differences in patient characteristics between anterior and posterior procedures in NRSIs, results from these studies should be interpreted cautiously.

Evidence was insufficient for fusion, neurologic function, general function, quality of life, mortality and serious adverse events, based on a combination of two or more of the following: high risk of bias, inconsistent findings, and lack of precision (Appendix G).

3.6.3 Detailed Analysis

3.6.3.1 Anterior Versus Posterior

The anterior approach used was anterior cervical foraminotomy (ACF) in one RCT,³² anterior cervical decompression without fusion (ACD) in one RCT,³⁴ and anterior cervical decompression and fusion (ACDF) in three RCTs³³⁻³⁵ and all four NRSIs.³⁶⁻³⁹ All studies used posterior cervical foraminotomy as the comparator.

3.6.3.1.1 Fusion

There was inadequate evidence to determine benefits and harms of anterior versus posterior surgical approaches on cervical fusion (SOE: Insufficient).

One RCT (N= 30) rated high risk of bias reported that no participants in either the ACF group or the posterior cervical foraminotomy group had radiologic evidence of instability on cervical x-rays at time of discharge or at a mean of 14 months.³² Authors did not define stability or criteria for determining fusion.

3.6.3.1.2 Pain

There were no differences in neck and arm pain between anterior versus posterior approaches in the short (3, 6 months) and intermediate term (12, 24 months) (SOE: Low); there was inadequate evidence to determine the benefits and harms of anterior versus posterior approaches on neck pain immediately post-operative (SOE: Insufficient).

At 12 months the proportion of ACDF vs. PCF patients experiencing a 26-point improvement (0-100 scale) in VAS neck pain (62% vs. 52%) or 41-point improvement in VAS neck pain (60% vs. 54%) was reported as comparable in one RCT (N=243);³⁵ an RR could not be calculated.

One small trial (N=30) rated high risk of bias reported that ACF was associated with lower neck pain VAS scores (0-10 scale) within a week of discharge ($p < 0.001$), however the reported confidence interval for the difference between groups suggested no difference (MD -3.13, 95% CI -4.52 to 1.75) and is likely a typographical error and should be (MD -3.13, 95% CI -4.52

3.6 Results, Key Question 5

to -1.75).³² One RCT (N=175) also rated high risk of bias, compared ACDF versus PCF at 3, 6, 12, and 24 months for arm pain VAS (0-100 scale), neck pain VAS (0-100 scale) and North American Spine Society (NASS) pain (0-6 scale).³³ The mean differences across measures did not change with time and there were no differences between ACDF and PCF in arm pain VAS (range from -1 to 1), neck pain VAS scores (range from 1 to 4) or NASS pain scores (range from -0.1 to 0.1) at any timepoint. Statistical tests were not reported and reported data were inadequate to calculate confidence intervals for effect sizes, but the authors noted that the clinical results were the same in both groups. The largest RCT (n=243, moderate quality) found no difference in VAS neck pain scores at 12 months (MD -2.70, 95% CI -9.67 to 4.27) or VAS arm pain (MD -2.80, 95% CI, -8.85 to 3.25).³⁵ Pooled estimates across the RCTs also reveal no difference in VAS arm pain at 12 months between ACDF and PCF (2 RCTs, N=403, MD -1.36, 95% CI -5.23 to 1.86, $I^2=0\%$; Appendix F Figure F-1).^{33,35} Across the same two RCTs, there was again no difference between ACDF and PCF in VAS neck pain (MD 0.31, 95% CI -6.20 to 5.81, $I^2=10.6\%$; Appendix F Figure F-2).^{33,35}

The fourth RCT (N=72) rated moderate risk of bias, reported similar rates of patient-reported complete or partial pain improvement (unvalidated measure) for anterior approaches (ACD and ACDF) versus PCF at day 1 postoperatively (100% vs. 100%, RR 1.00), at 2 months (98% vs. 100%, RR 0.98, 95% CI 0.94 to 1.02, $p=0.32$), and at approximately 60 months postoperatively (96.5% vs. 100%, RR 0.96, 95% CI 0.90 to 1.03, $p=0.32$).³⁴

Findings for pain from two NRSIs were consistent with those of the RCTs. The larger study (N=688) found no difference in mean scores for VAS arm pain (0-10 scale) at 3 months (4.20 vs. 3.82, MD 0.38, $p>0.05$), 12 months (4.06 vs. 4.07, MD 0.01, $p>0.05$) or 24 months (3.85 vs. 4.48, MD -0.63, $p>0.05$).³⁸ In the smaller NRSI (N=70) rated high risk of bias, there were no differences between ACDF versus PCF in VAS score (0-10 scale, not specified for arm or neck pain, 2.6 vs. 3.0, MD -0.4, $p=0.04$) at 12 months.³⁶ Reported estimates appear to be unadjusted.

3.6.3.1.3 Function

3.6.3.1.3.1 Neurologic Function

There was inadequate evidence to determine benefits and harms of anterior versus posterior approaches on neurologic function for all time points (SOE: Insufficient).

One RCT (N=175) rated high risk of bias³³ reported similar mean NASS neurology scores (0-6 scale) for ACDF and PCF and that no patient had deterioration of symptoms. Means were consistent at 3, 6, 12, and 24 months (range MD -0.2 to 0.2). Statistical tests were not reported and data were inadequate to calculate confidence intervals, but the authors noted that the clinical results were the same in both groups.

3.6.3.1.3.2 General Function

There was no difference in general function between anterior and posterior procedures based on NDI or Odom's criteria at 12 months in RCTs. (SOE: Low)

One moderate-quality RCT (N=243) reported that ACDF and PCF the proportion of responders was comparable based on NDI (defined as $\geq 17.3\%$ improvement, 0-100 scale; 63% vs. 66%; data were insufficient to calculate RR).³⁵ There was also no difference in mean change scores on NDI at 12 months (MD -1.2, 95% CI -5.8 to 3.5).

There was no difference in function between ACF and PCF at 12 months across two RCTs (N=273)^{32,35} based on Odom's criteria rating of excellent or good (2 RCTs, N= 273, 68.3% vs. 74.6%, RR 0.95, 95% CI 0.81 to 1.12, $I^2=0\%$) (Appendix F Figure F-3). In the larger trial

3.6 Results, Key Question 5

analysis with complete cases (N=204) at 1 year suggested that slightly fewer ACDF patients had excellent or good function, but the effect size is below the threshold for a small effect (76% vs. 88%, RR 0.87, 95% CI 0.76 to 0.99).³⁵

One NRSI (N=688), reported no difference between ACD and ACDF on the Core Outcome Measures Index-neck (COMI-neck, 0-10 scale), which has items for pain, function, symptom-specific well-being, quality of life and disability.³⁸ Mean changes in COMI-neck scores (0-10 scale) were similar at 3 months (-2.38 vs. -2.31, p=0.88) and 6 months (-2.94 vs. -2.67, p=0.55); at 24 months the mean COMI-neck scores were also similar (4.16 vs. 4.72, p>0.05; mean change not reported). The proportion of patients who achieved minimum clinically important difference on the COMI-neck score (decrease ≥ 2 points) was also similar at 3 months (50% vs. 56%, RR 0.89, 95% CI 0.65 to 1.24), 12 months (59% vs. 58%, RR 1.02, 95% CI 0.76 to 1.36), and 24 months (57% vs. 50%, RR 1.14, 95% CI 0.71 to 1.83). One NRSI (N=70) rated high risk of bias found no difference between ACDF versus PCF in Pain Disability Questionnaire functional status subscale scores (0 to 90 scale, 31.3 vs. 43.2, MD -11.9, p=0.30) or Pain Disability Questionnaire total score (52.8 vs. 69.6, p=0.50).³⁶ One RCT (N=175) rated high risk of bias reported Hilibrand criteria ratings (Poor, Satisfactory, Good, Excellent, measure not validated) for ACDF versus PCF at 3, 6, 12 and 24 months.³³ Data were not available to calculate effect sizes, but the authors noted that the clinical results were the same in both groups at all timepoints: Excellent (84% vs. 83% at 3 months, and 76% vs. 79% at 24 months).

3.6.3.1.4 Quality of Life

There was no difference in EuroQOL-5 Dimensions (EQ-5D, scale 0-1) at 12 months between ACDF and PCF in one RCT (SOE: Low).³⁵

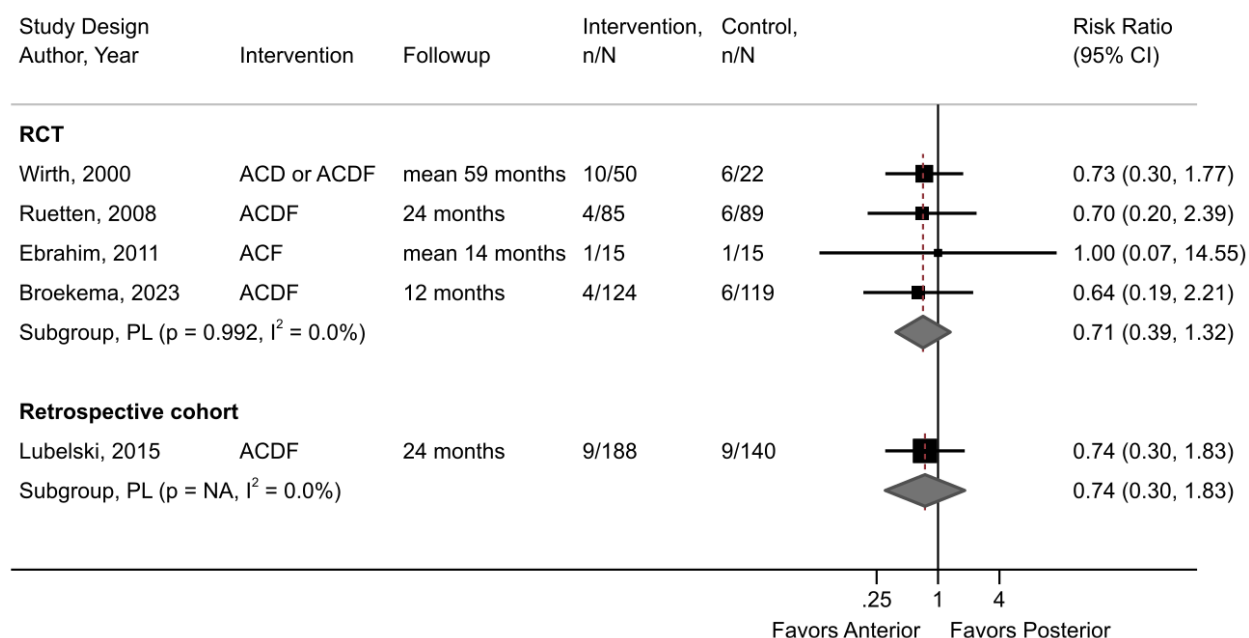
The RCT (N=243) found no difference on EQ-5D between ACDF and PCF in either the proportion of patient meeting a clinically important difference of 0.24 improvement (38% vs. 38%) or in change scores at 12 months (MD -0.01, 95% CI -0.06 to 0.10).³⁵ Similarly, one NRSI (N=70) rated high risk of bias found no difference in EuroQOL-5 Dimensions (EQ-5D, scale 0-1) at 12 months for ACDF (MD 0.69, 95% CI 0.61 to 0.77) versus PCF (MD 0.72, 95% CI 0.64 to 0.80, p=0.60).³⁶

3.6.3.1.5 Reoperation

There was no difference in the likelihood of reoperation between anterior and posterior procedures across four RCTs³²⁻³⁵ (2 of which were rated high risk of bias) or in one retrospective NRSI (N=328)³⁷ (Figure 3) (SOE: Low). Exclusion of the high risk of bias RCTs did not substantially change the estimate (2 RCTs, RR 0.70, 95% CI 0.30 to 1.61, I²= 0%).^{34,35}

3.6 Results, Key Question 5

Figure 3. Reoperation: anterior versus posterior cervical foraminotomy



ACF = anterior cervical foraminotomy, ACD = anterior cervical decompression without fusion; ACDF = anterior cervical discectomy and fusion; CI = confidence interval; PL = profile likelihood.

3.6.3.1.6 Harms

There were no differences in neurologic deficits between anterior and posterior approaches, although results were reported inconsistently (SOE: Low); reporting of other adverse events was limited (SOE: Insufficient).

Description and reporting of serious adverse events was limited. One RCT (N=243) reported similar rates of surgery-related adverse events for ACDF and PCF 6% in both groups).³⁵ Serious (not specified as surgery related) included: post-operative events (anaphylactic reaction to antibiotics, n=1, wound hematoma not requiring surgery, n=1, pulmonary embolism, n=1) and events requiring hospitalization (wound problems 0.8% vs. 1.7%, cardio-thoracic problems 0.08% vs. 2.5%). Slight cage subsidence was reported in one ACDF patient but there were no complaints and no reoperation was required.

Three RCTs (2 of which were rated high risk of bias) reported that no serious adverse events occurred for any patients.³²⁻³⁴ One RCT (N=72) that compared ACD and ACDF to PCF reported zero deaths.³⁴ One propensity score matched NRSI (N=46,598) reported higher 30-day mortality with ACDF versus PCF (MD 1 event per 10,000 cases, 95% CI 0.0 to 2.0 per 10,000 cases, p=0.012).³⁹ Although the MD is significant, it is small, suggesting the possibility of 0 to 2 deaths with PCF. Given that administrative data are subject to misclassification and potential for inadequate adjustment for confounders, this finding should be interpreted cautiously.

Neurologic deficits were reported inconsistently across studies. In one RCT (N=243) there was no difference in new radicular symptoms between ACDF and PCF recipients (3.2% vs. 0.8%, RR 3.84, 95% CI 0.43 to 33.85) as were persistent radicular symptoms (1.6% vs. 6.7%, RR 0.24, 95% CI 0.05 to 1.11); estimates are imprecise.³⁵ One RCT (N=72) found no difference in anterior versus posterior approaches for new weakness (8% vs. 14%, RR 0.59, 95% CI 0.14 to 2.40, p=0.46) or new numbness (6% vs. 9%, RR 0.66, 95% CI 0.12 to 3.68, p=0.63).³⁴ The other two RCTs reported specific neurologic deficits: in one small trial (N=30) no patients in either

3.6 Results, Key Question 5

group developed Horner's syndrome;³² the other trial (N=175) reported that no patients experienced damage to myelin resulting in paralysis of any degree.³³ One NRSI (N=70) reported that one patient who underwent PCF experienced C6 nerve injury, but did not provide data for patients who underwent ACDF.³⁶ Central nervous system complications at 30 days postoperatively was similar between anterior and posterior procedures in a large NRSI (N=46,598, MD 4 per 10,000, 95% CI -14 to 22 per 10,000).³⁹

Dysphagia was reported inconsistently across studies. One RCT (N=243), reported one case of unresolved dysphagia at 12 months in the ACDF group.³⁵ One RCT (N=175) reported transient difficulty swallowing for three patients who underwent ACDF and no patients who underwent PCF.³³ In a propensity score matched NRSI (N=46,598), ACDF was associated with higher rates of dysphagia/dysphonia at 30 days versus PCF (MD 14.5 per 1,000 cases, 95% CI 12.6 to 16.4 per 1000, $p<0.001$).³⁹ Neither study provided information on severity of dysphagia or need for intervention.

One large NRSI (N=46,598) reported that the following were rare but more common with ACDF versus PCF within 30 days after surgery: vascular injury (MD 2 per 10,000 cases, 95% CI 1 to 3 per 10,000 cases, $p=0.001$), cerebrospinal fluid leak (MD 2 per 10,000 cases, 95% CI 1 to 3 per 10,000 patients, $p=0.002$), and deep venous thrombus (9 per 10,000 cases, 95% CI 2 to 16 per 10,000 patients, $p=0.01$). There were no differences between anterior and posterior approaches for pulmonary embolism (MD 2 per 10,000, 95% CI -9 to 12 per 10,000 cases).³⁹

3.7 Results, Key Question 6

3.7 Key Question 6: In patients with cervical degenerative disease, what are the comparative effectiveness and harms of posterior versus anterior surgery in patients with greater than or equal to three level disease?

3.7.1 Key Findings

- There was low-strength evidence of no difference in neck pain, neurologic function and general function intermediate term (12 to 15 months) for ACDF versus posterior cervical decompression and fusion (PCDF) or laminoplasty for three or more levels (SOE: Low).
- The evidence for fusion, neck pain (short term), arm pain, neurologic function (short term) and quality of life was inadequate to draw conclusions (SOE: Insufficient).
- There was inadequate evidence to draw conclusions on reoperation rates between ACDF and posterior procedures (SOE: Insufficient).
- There was low-strength evidence that mortality and severe dysphagia did not differ between ACDF and laminoplasty or PCDF (SOE: Low).
- Rates of new neurologic complications and serious adverse events were inconsistently reported across studies and rare in general; there was low-strength evidence that posterior approaches were more commonly associated with a moderate to large increase in the odds of experiencing a neurologic adverse event and serious adverse event compared with ACDF (SOE: Low).

3.7.2 Description of Included Studies

One RCT⁴⁰ and nine NRSIs⁴¹⁻⁴⁹ compared anterior (i.e., ACDF) versus posterior surgery (i.e., laminoplasty, PCDF) at three or more levels for treatment of CDD (Appendixes C-D).

The RCT (N=34)⁴⁰ compared ACDF with posterior laminoplasty for participants with cervical spondylotic myelopathy (CSM) (71%) or ossification of the posterior longitudinal ligament (OPLL) (29%) involving three (71%) or four (29%) levels. Fewer participants randomized to ACDF were diagnosed with OPLL (24% vs. 35%), had four-level disease (18% vs. 41%) or were smokers (12% vs. 41%). Mean participant age was 62 years and 26 percent were female.⁴⁰ Race/ethnicity was not reported. Average followup time was 41 months. This trial was conducted in China and was rated high risk of bias.

Across the nine NRSIs, one prospective⁴⁴ and eight retrospective,^{41-43,45-49} sample sizes ranged from 245 to 13,884 (total N=41,982). The average study patient age was 61 years (range 54 to 63 years) and 43 percent were female (range 31% to 52%). Three studies reported race/ethnicity (White: range 65.5% to 82.3%; Black: 12.3% to 17.0%; Hispanic: 0.5%; Other: 17.7% to 19.1%).^{41,47,48} The anterior approach was ACDF (with or without corpectomy) in all nine studies⁴¹⁻⁴⁹ and also included anterior cervical corpectomy and fusion in one study.⁴³ The posterior approach was PCDF in six studies,^{41,42,44-46,48} laminectomy and fusion in two studies^{43,47} and laminoplasty in two studies.^{47,49} Two studies included three treatment groups; one with two anterior arms⁴³ and one with two posterior arms.⁴⁷ The number of involved levels varied across the studies but most included three to five levels; one study included only three levels⁴⁸ and another only four levels.⁴⁵ One NRSI was rated low risk of bias⁴⁶ and the remainder were rated moderate risk of bias.^{41-45,47-49} Given the potential for confounding by indication and differences in patient population between those receiving posterior versus anterior procedure, particularly in the NRSI, results should be interpreted cautiously.

3.7 Results, Key Question 6

Evidence was insufficient for fusion, pain (short and long term), neurologic function (short term), quality of life, and reoperation based on a combination of two or more of the following: high risk of bias, inconsistent findings, and lack of precision (Appendix G).

3.7.3 Detailed Analysis

3.7.3.1 Fusion

There was inadequate evidence to determine the benefits and harms of anterior versus posterior surgical approaches on fusion in participants with three or more level disease (SOE: Insufficient).

One retrospective NRSI that used propensity score matching (N=12,248) found that PCDF was associated with substantially higher odds of pseudarthrosis at 12 months compared with ACDF (odds ratio [OR] 2.43, 95% CI 1.96 to 3.01) at three levels.⁴⁸ The RCT did not report fusion.

3.7.3.2 Pain

There was low-strength evidence of no difference in neck pain in the intermediate term (SOE: Low); there was inadequate evidence for neck pain in the short term and arm pain in the intermediate term in participants with three or more level disease (SOE: Insufficient).

One RCT (N=32) rated high risk of bias reported no differences between 3- or 4-level ACDF and laminoplasty in neck pain scores (VAS, 0-10 scale) at 3 months (MD -0.10, 95% CI -0.46 to 0.26) and 6 months (MD 0, 95% CI -0.18 to 0.18) or at 12 months (MD 0.10, 95% CI -0.23 to 0.43) and 15 months (MD -0.10, 95% CI -0.44 to 0.24).⁴⁰ Similarly, there were no differences between ACDF (with and without corpectomy) and PCDF at three to five levels for NRS (0-10) neck pain scores (median 2 vs. 2, adjusted OR 0.67, 95% CI 0.37 to 1.21) or arm pain scores (median 1 vs. 0.5, adjusted OR 0.99, 95% CI 0.51 to 1.93) at 12 months in one retrospective NRSI (N=245).⁴¹

3.7.3.3 Function

3.7.3.3.1 Neurologic Function

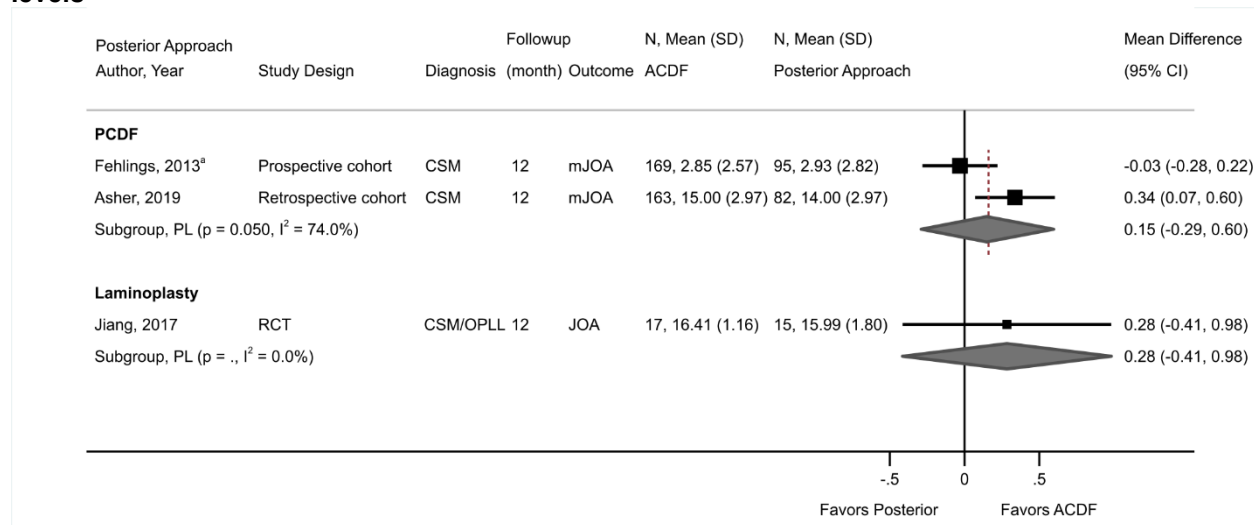
There was low-strength evidence of no difference in neurologic function between anterior and posterior approaches in participants with three or more level disease in the intermediate term (SOE: Low); there was inadequate evidence for determining the benefits and harms on neurologic function in the short term (SOE: Insufficient).

There was no difference in neurologic function at intermediate term (12 months) in one small RCT rated high risk of bias (N=32, MD 0.28, 95% CI -0.41 to 0.98, Japanese Orthopaedic Association Scale [JOA] scores, 0-18 scale)⁴⁰ and two NRSIs rated moderate risk of bias (N=506, MD 0.15, 95% CI -0.29 to 0.60, $I^2=74.0\%$, mJOA scores, 0-18 scale)^{40,41,44} that compared ACDF with posterior laminoplasty (RCT) or PCDF (NRSIs) for 3- to 5-level disease (Figure 4) (SOE: Low). There was also no difference between groups in JOA scores short term in the RCT (N=32): 3 months (MD -0.40, 95% CI -1.76 to 0.96) and 6 months (MD 0.20, 95% CI -1.14 to 1.54).⁴⁰ The pooled estimate across the two NRSIs had substantial heterogeneity (Figure 4), which may be due in part to different study designs, variables controlled for in multivariate analyses, and types of posterior procedures used. The prospective NRSI⁴⁴ showed no difference between groups and included patients who underwent laminoplasty (14%) (all

3.7 Results, Key Question 6

others had PCDF); it was unclear which baseline confounders were controlled for in this study. The retrospective NRSI⁴¹ showed a large improvement with ACDF versus PCDF approaches; multivariate logistic regression models controlled for 19 different baseline variables.

Figure 4. Neurologic function (JOA or mJOA scores): anterior versus posterior approaches for ≥3 levels



ACDF = anterior cervical discectomy and fusion; CI = confidence interval; CSM = cervical spondylotic myelopathy; JOA = Japanese Orthopaedic Association; mJOA = modified Japanese Orthopaedic Association; OPLL = ossification of the posterior longitudinal ligament, PCDF = posterior cervical decompression and fusion; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation.

^a Posterior approach included laminoplasty (14% of patients) or laminectomy and fusion (86% of patients)

One prospective NRSI (N=264) assessed neurologic function with the Nurick score (0-5 scale) and found no difference between 3- to 5-level ACDF and posterior approaches (laminectomy and fusion [86%] or laminoplasty [14%]) in mean change from baseline to 12 months after adjusting for baseline characteristics (MD in change scores 0.19, 95% CI -0.20 to 0.58⁴⁴).

3.7.3.3.2 General Function

There were no differences between anterior and posterior surgery for 3- to 5-level disease at intermediate term (12 months) for any function measure reported across two NRSIs (N=509)^{41,44} (SOE: Low). One prospective NRSI (N=264) compared ACDF with laminectomy and fusion (86%) or laminoplasty (14%) and reported the change in NDI scores compared with baseline (MD in change scores -0.97, 95% CI -7.15 to 5.21, scale unclear), SF-36 PCS scores (MD in change scores -1.90, 95% CI -5.30 to 1.50, 0-100 scale) and SF-36 MCS scores (MD in change scores 0.42, 95% CI -2.30 to 3.14, 0-100 scale).⁴⁴ One retrospective NRSI (N=245) compared ACDF (with and without corpectomy) with PCDF and reported median NDI scores (16 vs. 17, adjusted OR 0.76, 95% CI 0.42 to 1.37)⁴¹ (SOE: Low).

3.7.3.4 Quality of Life

There was inadequate evidence to determine the benefits and harms of anterior versus posterior approaches on quality of life in participants with three or more level disease (SOE: Insufficient).

3.7 Results, Key Question 6

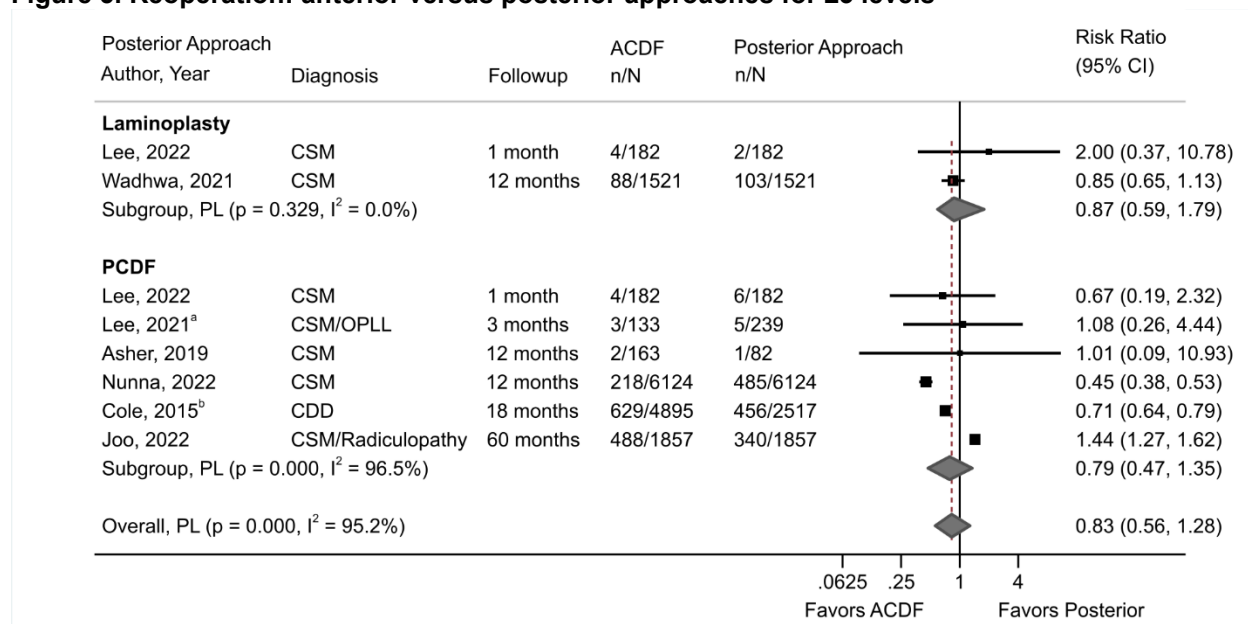
One retrospective cohort study (N=245) found no difference between 3- to 5-level ACDF (with and without corpectomy) and PCDF in EQ-5D scores intermediate term at 12 months (adjusted odds ratio 1.36, 95% CI 0.76 to 2.44, referent = ACDF) after adjusting for a number of baseline variables.⁴¹

3.7.3.5 Reoperation

There was inadequate evidence to draw conclusion on reoperation rates between ACDF and posterior procedures (SOE: Insufficient).

Seven NRSIs (N=27,579) that compared ACDF with posterior procedures at three or more levels reported reoperation/revision rates.^{41,43,45-49} In pooled analysis at any timepoint based on longest followup (range 1 to 60 months), there were no differences between ACDF versus laminoplasty (2 NRSIs, N=3,406, 5.4% vs. 6.2%, RR 0.87, 95% CI 0.59 to 1.79, $I^2=0\%$)^{47,49} or PCDF (6 NRSIs, N=24,355, 10.1% vs. 11.8%, RR 0.79, 95% CI 0.47 to 1.35, $I^2=96.5\%$),^{41,43,45-48} however, heterogeneity was substantial for the latter comparison (Figure 5). Exclusion of one outlier study⁴⁵ at 60 months that included patients with both myelopathy and radiculopathy reduced heterogeneity slightly and resulted in a moderate reduction in the likelihood of reoperation for ACDF compared with PCDF at any timepoint (1-18 months, 5 NRSIs, N=20,641, 7.4% vs. 10.4%, RR 0.59, 95% CI 0.42 to 0.95, $I^2=82.4\%$).^{41,43,46-48} These results were driven by two large administrative database studies.^{43,48} There was no difference between ACDF and PCDF at 1 to 3 months (2 NRSIs, N=736, RR 0.82, 95% CI 0.32 to 2.08, $I^2=0\%$).^{46,47} ACDF was associated with a higher risk of reoperation compared with PCDF (N=3,714, RR 1.44, 95% CI 1.27 to 1.62) in one study at 60 months.⁴⁵ It is challenging to draw firm conclusions from this data as definitions of reoperation and revision varied or were not specified across the studies, there were differences in posterior approach used, and the pooled estimates were mainly driven by two large administrative data studies.

Figure 5. Reoperation: anterior versus posterior approaches for ≥3 levels



ACCF = anterior cervical corpectomy and fusion; ACDF = anterior cervical discectomy and fusion; CI = confidence interval; CSM = cervical spondylotic myelopathy; OPLL = ossification of the posterior longitudinal ligament, PCDF = posterior cervical decompression and fusion; PL = profile likelihood.

^a Study included patients with myelopathy and OPLL

3.7 Results, Key Question 6

^b Anterior approach included ACDF or ACCF

One large NRSI (N=12,248) that used administrative data and propensity score matching reported reoperation outcomes that could not be included in the meta-analysis.⁴⁸ PCDF was associated with substantially higher odds of wound-specific revision surgery at 1 month (1.2% vs. 0.4%, OR 3.02, 95% CI 2.56 to 3.49) and moderately lower odds of additional anterior or posterior fusion at 12 months (4.3% vs. 7.0%, OR 0.60, 95% CI 0.44 to 0.76) compared with ACDF at three levels.

3.7.3.6 Harms

3.7.3.6.1 Neurologic Deficits

There was low-strength evidence that posterior approaches were more likely associated with a moderate to large increase in the odds of experiencing a neurologic adverse event compared with ACDF (SOE: Low). Reporting of neurological events varied across one RCT (N=32)⁴⁰ and six NRSIs (total N=37,095, range 245 to 13,884).^{41-44,48,49} The RCT reported no cases of postoperative worsening of myelopathy or C5 root palsy with either 3- or 4-level ACDF versus posterior laminoplasty.⁴⁰ Central nervous system complications (not further defined) were rare through 90 days after ACDF (<0.7%) and posterior laminoplasty (0.9%) at three or more levels in one NRSI (N=3,042).⁴⁹ Two NRSIs reported that PCDF was associated with moderately higher odds of “neurological complications” compared with ACDF at three or more levels but did not provide further details: 0.59% vs. 0.35% (adjusted OR 1.7, 95% CI 1.0 to 2.8) immediately postoperative in one study (N=13,884)⁴² and 1.8% vs. 1.1% (OR 1.6, 95% CI 1.08 to 2.38) at 1 month in another (N=7,412).⁴³ Two other NRSIs reported no difference between ACDF and PCDF at three to five levels in new neurological deficits (N=264, 4.1% vs. 3.2%, RR 1.31, 95% CI 0.35 to 4.95)⁴⁴ or new motor deficits (N=245, 2% vs. 0%)⁴¹ at 12 months. One large NRSI (N=12,248) reported no difference between PCDF and ACDF in the incidence of postoperative coma (0.4% vs. 0.6%, OR 1.26, 95% CI 0.75 to 1.77).⁴⁸

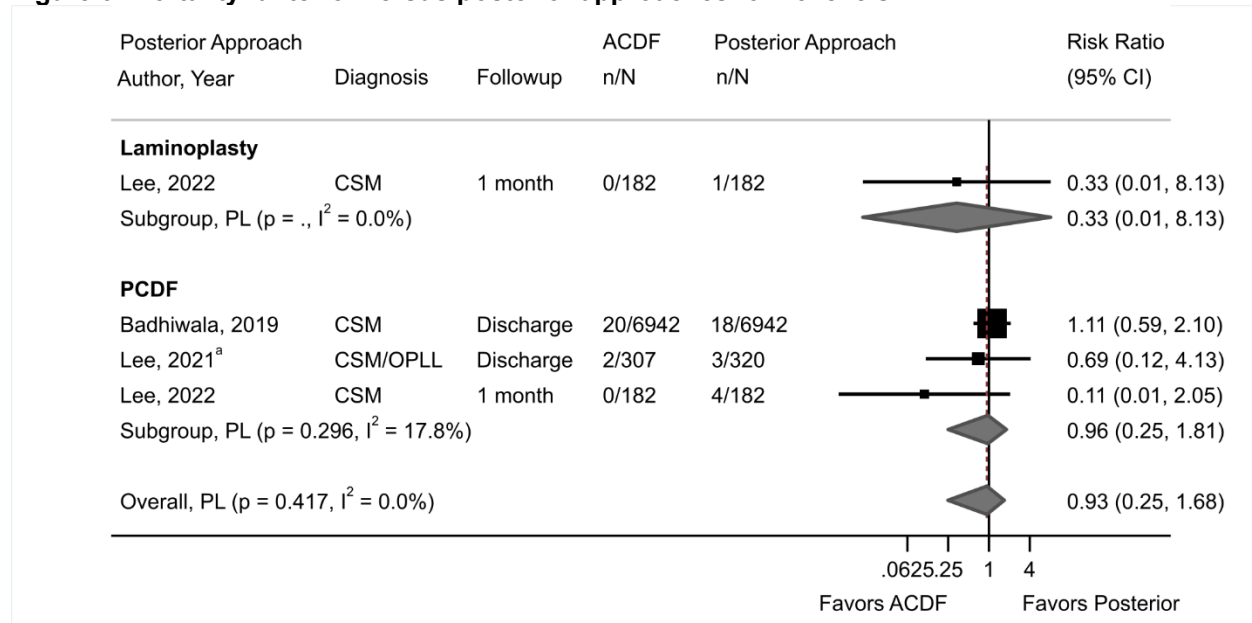
3.7.3.6.2 Mortality

There was low-strength evidence that mortality did not differ between ACDF and laminoplasty or PCDF (SOE: Low).

Three NRSIs (total N=15,057, range 546 to 13,884) that compared anterior with posterior approaches at three or more levels found no difference in short-term mortality after ACDF versus posterior laminoplasty at 1 month (1 NRSI, N=364, 0% vs. 0.05%, RR 0.33, 95% CI 0.01 to 8.13)⁴⁷ and ACDF versus PCDF at hospital discharge to 1 month (3 NRSIs, N=14,875, 0.3% vs. 0.3%, RR 0.96, 95% CI 0.25 to 1.81, $I^2=17.8\%$)^{42,46,47} (Figure 6). One NRSI (N=12,248) reported no deaths in either arm (ACDF vs. PCDF) and was unable to be included in the pooled analysis.⁴⁸

3.7 Results, Key Question 6

Figure 6. Mortality: anterior versus posterior approaches for ≥3 levels



ACDF = anterior cervical discectomy and fusion; CI = confidence interval; CSM = cervical spondylotic myelopathy; OPLL = ossification of the posterior longitudinal ligament, PCDF = posterior cervical decompression and fusion; PL = profile likelihood. ^a Study included patients with myelopathy and OPLL

3.7.3.6.3 Dysphagia

There was low-strength evidence that the likelihood of experiencing severe dysphagia did not differ between ACDF and laminoplasty or PCDF (SOE: Low).

Severe dysphagia was rare across two NRSIs that compared ACDF with PCDF or posterior laminoplasty. There were two cases (1%) requiring a nasogastric tube in one study (N=245)⁴¹ and one case (0.5%) requiring an unplanned readmission 11 days post surgery in the other (N=364),⁴⁷ all three cases occurred in the ACDF arms (SOE: Low).

One RCT (N=32)⁴⁰ and seven NRSIs (total N=41,172, range 245 to 13,884)^{41-43,45,46,48,49} also reported dysphagia but did not report the severity; frequencies ranged from 2.7 to 14.0 percent after ACDF and from 0 to 3.6 percent after PCDF across six NRSIs (N=38,130),^{41-43,45,46,48} most of which reported a substantial to moderate decrease in the odds/risk of dysphagia with PCDF (OR range 0.20 to 0.61), and from <0.7 to 5.9 percent versus 0 to <0.7 percent in the ACDF versus laminoplasty arms, respectively, across one small RCT (N=32)⁴⁰ and one large NRSI (N=3,042), with no differences between treatments.⁴⁹

3.7.3.6.4 Serious Adverse Events

There was low-strength evidence that posterior approaches were more likely associated with a moderate to large increase in the odds of experiencing a serious adverse event compared with ACDF (SOE: Low).

One RCT (N=32) reported that intraoperative dural tear occurred in 5.9 percent of ACDF versus 11.8 percent of PCDF patients (RR 0.50, 95% CI 0.05 to 5.01) and that there were no cases of instrumentation failure or malposition, infection or hematoma.⁴⁰

Across the NRSIs, reporting of serious adverse events varied; adverse events generally occurred more often with posterior approaches versus ACDF.

3.7 Results, Key Question 6

Thrombotic events were rare across eight NRSIs (total N=41,718, range 245 to 13,884) with followup immediately postoperative to 12 months.^{41-43,45-49} The frequency of deep vein thrombosis (DVT) or pulmonary embolism ranged from 0 to 2.3 percent (ACDF) versus 0 to 4.3 percent (PCDF or posterior laminoplasty). Four of the studies (N=37,258) reported that posterior approaches were associated with moderate to large increases in the odds of experiencing a thrombotic event compared with ACDF (range of ORs 1.75 to 3.7).^{42,43,45,48}

Stroke/cerebrovascular events occurred variably across three NRSIs with short-term followup (1 to 3 months); one study (N=546) reported no events in either arm (ACDF vs. PCDF or posterior laminoplasty),⁴⁷ one study (N=627) reported more events after ACDF (1.8% vs. 0% PCDF, p=0.016),⁴⁶ while the third found that PCDF was associated with a large increase in the odds of stroke compared with ACDF (N=12,248, 4.2% vs. 2.5%, OR 1.68, 95% CI 1.48 to 1.89).⁴⁸

Sepsis was rare across three NRSIs (total N=7,302, range 546 to 3,714).^{45,47,49} One study reported substantially higher odds of having sepsis within 3 months after PCDF compared with ACDF (N=3,714, 2.5% vs. 0.7%, adjusted OR 3.56, 95% CI 1.96 to 6.91)⁴⁵ while the other two studies (N=3,588) reported similar rates between groups (ACDF, range <0.7% to 1.1% vs. PCDF/posterior laminoplasty, range <0.7% to 1.7%)^{47,49}

Surgical site infection was reported by four NRSIs. Three studies (N=22,702)^{43,48,49} reported that posterior approaches (PCDF or laminoplasty) were associated with a large increase in the odds of surgical site infection compared with ACDF at 1 to 3 months (frequency range 2.4% to 4.7% vs. 0.8% to 1.0%, OR range 3.1 to 3.7) and the fourth (N=245) found no difference between groups (1% each).⁴¹

Wound dehiscence was infrequent across four NRSIs, two of which reported that PCDF was associated with a substantial increase in the odds of experiencing this complication compared with ACDF (N=19,660, frequency range 1.3% to 2.7% vs. 0.1% to 0.5%, range of ORs 5.6 to 10.8)^{43,48} and two that found no difference between groups (1% each, N=245, 1 RCT)⁴¹ and (0% each, N=264, 1 RCT).⁴⁴

Dural tear/durotomy occurred more often with ACDF versus PCDF in one study (N=627, 9.4% vs. 3.2%, RR 3.02, 95% CI 1.50 to 6.10)⁴⁶ while no events were reported in either group in another study (N=264).⁴⁴

One NRSI found that PCDF was associated with a large increase in the odds of having any severe adverse event through 3 months compared with ACDF (N=3,714, 13% vs. 6.1%, OR 2.31, 95% CI 1.83 to 2.93).⁴⁵

A variety of other serious adverse events were reported across five NRSIs (total N=21,813, range 546 to 13,884);^{42,45-47,49} event rates ranged from 0.04 to 4.5 percent in the ACDF arms and from 0 to 7.7 percent in the posterior arms (PCDF or laminoplasty) and included kidney injury (4 studies)^{45-47,49} cardiac complications (4 studies),^{42,46,47,49} transfusion (3 studies),⁴⁵⁻⁴⁷ respiratory complications (3 studies),^{42,46,49} and arterial injury and hardware instrument failure malposition (1 study).⁴² Excluding perioperative blood transfusion in one study, which had the highest frequency of events across all these complications (N=627, 4.5% with ACDF vs. 7.7% with a posterior approach),⁴⁶ the range across treatment arms was 0 to 3.7 percent (ACDF) versus 0.06 to 3.6 percent (posterior approach). There were no cases of myocardial infarction or vocal cord paralysis in one NRSI (N=245).⁴¹

3.8 Results, Key Question 7

3.8 Key Question 7: In patients with cervical spondylotic myelopathy due to cervical degenerative disease, what are the comparative effectiveness and harms of cervical laminectomy and fusion compared to cervical laminoplasty?

3.8.1 Key Findings

- Evidence was inadequate to determine the effect of laminectomy versus laminoplasty on neck, shoulder, or arm pain (SOE: Insufficient).
- There was moderate-strength evidence of little difference between laminectomy and fusion versus laminoplasty on neurologic function (SOE: Moderate) and low-strength evidence of no difference between laminectomy and fusion versus laminoplasty on general function (SOE: Low).
- There was moderate-strength evidence of no difference in reoperation rates between laminectomy and fusion compared with laminectomy (SOE: Moderate).
- There was low-strength evidence of fewer complications with laminoplasty compared with laminectomy and fusion (SOE: Low).

3.8.2 Description of Included Studies

Two RCTs (N=46)^{50,51} and 6 NRSI (N=15,523)⁵²⁻⁵⁷ compared cervical laminectomy and fusion with cervical laminoplasty (Appendix C). The followup duration was 1 year in both of the RCTs and ranged from 1 year to 5 years in the nonrandomized studies. Trials were conducted in the United States and Egypt, with NRSI studies conducted in the United States (3 studies), Japan, China, and a multinational setting.

The mean age of participants was 58 years in one trial and not reported in the other (most participants in the second trial ranged from 50 to 59 years); mean ages in the nonrandomized studies ranged from 54 to 64 years. The average proportion of females in the trials was 30 and 58 percent; the proportion of females in the NRSI studies ranged from 21 to 55 percent. Race and ethnicity were not reported in any of the studies. One trial enrolled patients with at least 3 levels of spinal cord compression,⁵⁰ while the other did not report the number of disease levels.⁵¹ Two nonrandomized studies enrolled patients with 3 or more levels of spinal cord compression,^{54,57} whereas the number of disease levels was not specified in the other NRSI studies.

One RCT was rated high risk of bias⁵⁰ and the other was rated as moderate risk of bias.⁵¹ All of the observational studies were rated moderate risk of bias (Appendix D). The evidence comparing laminectomy and fusion with laminoplasty for neck, shoulder, and arm pain was rated insufficient due to limited and conflicting evidence (Appendix G).

3.8.3 Detailed Analysis

3.8.3.1 Fusion

No study reported fusion outcomes in the laminectomy fusion arm only.

3.8.3.2 Pain

There was inadequate evidence to determine the benefits and harms of laminectomy and fusion compared with laminoplasty on neck, shoulder, or arm pain (SOE: Insufficient).

3.8 Results, Key Question 7

One RCT (N=30) found a moderate benefit in neck pain with laminectomy and fusion compared with laminoplasty at 1 year (MD -1.33, $p<0.05$) but no difference in limb pain (MD 0.4, $p>0.05$).⁵⁰ The other RCT (N=16) reported improvement in neck and arm pain from baseline only in patients who underwent laminoplasty (surgical approaches not directly compared, numeric values not reported, $p<0.05$, both outcomes).⁵¹

Among the nonrandomized studies assessing neck^{52,54} or shoulder⁵² pain, two (N=148) reported no differences in VAS scores between laminectomy and fusion and laminoplasty at 1 or 3 years.^{52,54} Another observational study (N=121) reported no differences in improved pain (74% vs. 60%; $p=0.141$) for posterior laminectomy and fusion versus laminoplasty.⁵⁷

3.8.3.3 Function

3.8.3.3.1 Neurologic Function

There was moderate-strength evidence of no difference between laminectomy and fusion versus laminoplasty on neurologic function (SOE: Moderate).

Two head-to-head RCTs (N=46) assessed neurologic function with the mJOA and the Nurick Classification Scale for Spinal Cord Compression (i.e., Nurick's grade 0 to 5) at 1 year postoperative.^{50,51} Pooled analysis of the two trials found no difference in function between cervical laminectomy and fusion versus laminoplasty using the mJOA (N=46, MD -0.03, 95% CI -0.68 to 0.74, $I^2=76%$).^{50,51} One trial reported no significant difference between laminectomy and fusion compared with laminoplasty in Nurick grade (1.40 vs. 1.67; $p=0.23$),⁵⁰ while the other trial reported a significant pre-post difference for laminoplasty only (numeric values not reported; $p<0.05$).⁵¹

Four nonrandomized studies reported neurologic function using the mJOA or JOA score; three reported no difference between laminectomy and fusion versus laminoplasty^{52,54,57} and one reported a significant benefit of laminoplasty over laminectomy and fusion (mean mJOA at 2 years: 3.49, 95% CI 2.84 to 4.13 vs. 2.39, 95% CI 1.91 to 2.86; $p=0.0069$).⁵³ However, this study reported no significant difference in Nurick's grade at 2 years (mean 1.57, 95% CI 1.23 to 1.90 vs. 1.18, 95% CI 0.92 to 1.44; $p=0.077$).

3.8.3.3.2 General Function

There was low-strength evidence of little difference between laminectomy and fusion versus laminoplasty on general function (SOE: Low).

Neck disability scores on the NDI were not different between laminectomy and fusion versus laminoplasty 1-year postoperatively (1 RCT, N=30, MD 3.86, $p=0.2$)⁵⁰ and only improved with laminoplasty in the other trial (N=16, surgical approaches not directly compared, numeric values not reported, $p=0.05$).⁵¹ The same trial (N=16) reported improvement from baseline on the SF-36 with laminoplasty only (numeric values not reported, $p<0.05$).^{51,52,54} Two NRSIs reported no differences on the NDI,^{52,53} and three reported no differences between surgical approaches in SF-12 or SF-36 PCS or MCS scores.⁵²⁻⁵⁴ Another observational study reported no differences in improved gait (71% vs. 68%; $p=0.674$) as assessed on a 5-point NRS.⁵⁷

3.8.3.4 Quality of Life

No study reported quality of life outcomes.

3.8 Results, Key Question 7

3.8.3.5 Harms

There was moderate-strength evidence of no difference between laminectomy and fusion compared with laminectomy in reoperation rates (SOE: Moderate) and low-strength evidence of fewer complication overall with laminoplasty compared with laminectomy and fusion (SOE: Low).

Both trials reported no significant differences in harms, though event rates were low.^{50,51} Likewise, four NRSI studies (N=582) found no differences in infection, device failure, or reoperation rates.^{52-54,57} A large database study (PearlDiver Mariner Database, N=11,860, unsure of matched sample size)⁵⁵ reported similar revision rates for laminoplasty and laminectomy with fusion (5.63% vs. 5.90%, p=0.62) at 1 year but fewer surgical site infections (matched OR 0.60; p=0.002), wound complications (matched OR 0.67, p=0.002) and dysphagia (matched OR 0.77; p=0.01) with laminoplasty compared with laminectomy and fusion.⁵⁵ Also reported in this study were reduce rates of spinal cord injury (matched OR 0.6, p=0.02), limb paralysis (matched OR 0.67, p<0.001), respiratory failure (matched OR 0.74, p=0.01), renal failure (matched OR 0.84, p=0.04), and sepsis (matched OR 0.85, p=0.04) with laminoplasty versus laminectomy and fusion. No complication was reported more likely with laminoplasty. An earlier propensity-matched analysis of patients from this same database (N=928) found lower revision rates at 1 year with laminoplasty versus laminectomy and fusion (2.4% vs. 7.1%; p<0.001).⁵⁶ The dissimilar findings may be due a larger sample size (this is an assumption as the matched sample size was not reported in the later study) to changes in surgical methods and/or skill of the surgeon over time. Two additional NRSI studies reported no differences in dysphagia between groups.^{53,57}

3.9 Results, Key Question 8

3.9 Key Question 8: In patients with cervical spondylotic radiculopathy or myelopathy at one or two levels, what are the comparative effectiveness and harms of cervical arthroplasty compared to anterior cervical discectomy and fusion?

3.9.1 Key Findings

- In participants receiving single-level interventions:
 - There was moderate-strength evidence of no difference between cervical arthroplasty and ACDF in likelihood of success (response) for any pain or function measure at short, intermediate, and long term (SOE: Moderate).
 - There were also moderate-strength evidence of no differences between cervical arthroplasty and ACDF in pain or function at short, intermediate, or long term: neck or arm pain, neurologic status or general function (SOE: Moderate).
 - There was high-strength evidence that cervical arthroplasty was associated with substantially lower likelihood of reoperation at the index level versus ACDF (SOE: High).
 - There was low-strength evidence that cervical arthroplasty was associated with slightly lower likelihood of any serious adverse event at short term versus ACDF, but there were no differences at times >24 months and serious adverse events were variably defined (SOE: Low for all times).
 - There was low-strength evidence of no differences in neurological events or deficits between cervical arthroplasty and ACDF at short, intermediate, or long term (SOE: Low).
 - There was inadequate evidence on the likelihood of mortality between cervical arthroplasty and ACDF (SOE: Insufficient).
- In participants receiving 2-level interventions:
 - There was moderate-strength evidence of no differences between cervical arthroplasty and ACDF on pain (neck or arm), neurologic function and general function at short, intermediate, and long term (SOE: Moderate).
 - Reoperation at the index level was substantially less likely with cervical arthroplasty at all times reported (24 to >60 months) (SOE: Low).
 - Cervical arthroplasty was associated with slightly lower likelihood of serious adverse events compared with ACDF at 24 months, but there was no difference between procedures at 120 months for World Health Organization (WHO) Grade 3 or 4 (scale 0-4, 4 most serious) adverse events (SOE: Low).
 - Evidence for neurological deficits or events and for mortality was inadequate to draw conclusions (SOE: Insufficient).
- In participants receiving 1-, 2- or 3-level interventions
 - There was no difference between cervical arthroplasty and ACDF in VAS neck pain scores at intermediate term (SOE: Low).
 - Evidence was inadequate to draw conclusions for neurologic and general function and harms (SOE: Insufficient).

3.9 Results, Key Question 8

3.9.2 Description of Included Studies

Twenty-two RCTs in 45 publications (N=4,120) compared cervical arthroplasty with ACDF (Appendix C).⁵⁸⁻¹⁰² The average followup duration was 56 months (range 6 to 108 months). Eight trials each were conducted in the United States^{65,72,75,76,86,87,93,98} and in China;^{61-63,79,91,99-101} two trials in Germany;^{89,90} and one trial each in India,⁷⁴ the Netherlands,¹⁰³ Spain,⁶⁴ and Turkey.⁸²

The average study mean age of participants was 45 years (range 37 to 50 years); the average proportion of females in studies was 47 percent (range 20% to 63%). Five trials reported race, four enrolling mostly White participants (range 89% to 93%)^{72,76,93,98} and the other enrolling Han (Chinese) participants.⁶³ One trial reported ethnicity, enrolling mostly non-Hispanic participants (94%).⁶⁵

Studies enrolled participants with clinical and/or radiological evidence of cervical radiculopathy and/or myelopathy, although only three trials reported baseline values.^{64,74,89} Participants had 1-level disease in 15 trials (N=3,036),^{61,75,76,79,82,86,87,89-91,93,98,100,101,103} 2-level disease in four trials (N=872),^{63,65,72,99} and mixed-level (1, 2 or 3) disease in three trials (N=196).^{62,64,74} Of the single-level trials, six (in 23 publications) were US Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trials^{58-60,67,68,70,75-78,80,81,84-87,92,93,95-98,102} and of the 2-level trials, two (in 9 publications) were IDE trials.^{65,66,71-73,80,83,94,95}

Six trials were rated low risk of bias,^{65,76,79,86,87,93} six trials were rated high risk of bias,^{61,64,82,90,91,101} and the remainder were rated moderate risk of bias^{62,63,72,74,75,89,98-100,103} (Appendix D). Methodological limitations included unclear randomization techniques, unclear blinding, and high attrition.

Two prospective, multicenter NRSIs (N=349 and N=352) of recently completed FDA IDE trials compared newer cervical arthroplasty devices (M6-C and Simplify discs) with historic ACDF controls (Appendix C).^{104,105} Propensity score matching was done to facilitate baseline comparability between groups. Followup was 24 months in both studies. One study enrolled participants with clinical and radiological evidence of cervical radiculopathy with or without myelopathy at 1-level¹⁰⁵ and the other study enrolled participants with cervical radiculopathy and/or myelopathy at 2-levels.¹⁰⁴ The study mean ages of participants were 45 years and 48 years and the proportion of females were 50 and 52 percent. Race/ethnicity was not reported by either study. The study mean body mass indexes were 27.5 and 28.9. Both studies were conducted in the United States and were rated moderate risk of bias (Appendix D).

Eight non-IDE NRSIs were included for the evaluation of harms only and included seven large database/registry studies,¹⁰⁶⁻¹¹² one a post-hoc analysis of an FDA IDE trial¹¹³ (Appendix C). Sample sizes ranged from 342 to 143,060 (total N=206,887). The average study mean age of patients was 50 years (range 46 to 54 years) and the proportion of females was 51 percent (range 50% to 52%). Across three studies most patients were White (82%; range 81% to 85%); one study reported 94 percent of patients were non-Hispanic¹¹³ and four studies did not report race/ethnicity.¹⁰⁹⁻¹¹² Two studies^{107,113} enrolled patients with radiculopathy and/or myelopathy; three studies^{106,111,112} specifically excluded patients with myelopathy and the remaining three studies¹⁰⁸⁻¹¹⁰ only stated that patients had CDD. Followup ranged from 30 days to 84 months. One study took place in Germany,¹¹⁰ and all others in the United States. Four studies were rated moderate risk of bias^{107,111-113} and four high risk of bias^{106,108-110} (Appendix D).

For the FDA IDE trials, an attempt was made to reconcile conflicting information among multiple reports presenting the same data and when necessary, we used the data from the FDA Summary of Safety and Effectiveness Data (SSED): 1-level¹¹⁴⁻¹²⁰ and 2-level indications.¹²¹⁻¹²³

3.9 Results, Key Question 8

For measures of success, we focused on the FDA required definition and reported alternative definitions as applicable. Only FDA approved devices are included for this Key Question.

In the results below for benefits, we report outcomes according to the following timeframes: short term (<12 months), intermediate term (12 to 60 months) and long term (>60 months).

Evidence was insufficient for mortality (all levels), neurologic deficit/events (2-levels and mixed 1-, 2- or 3-levels), and neurologic function, general function, reoperation and serious adverse events (mixed 1-, 2- or 3-levels) based on a combination of two or more of the following: high risk of bias, inconsistent findings, and lack of precision (Appendix G).

3.9.3 Detailed Analysis

3.9.3.1 Single-Level Cervical Arthroplasty Versus ACDF

Fifteen trials (N=3,036) (in 33 publications) compared single-level cervical arthroplasty and ACDF, including six FDA IDE trials (in 23 publications)^{58-60,67,68,70,75-78,80,81,84-87,92,93,95-98,102} and nine non-IDE trials (in 10 publications),^{61,79,82,89-91,100,101,103} as did one FDA IDE NRSI.¹⁰⁵ Six additional NRSIs compared harms for single-level cervical arthroplasty and ACDF.^{106-110,113}

3.9.3.1.1 Fusion

Seven RCTs (across 15 publications) (N=2,382) that compared single-level cervical arthroplasty and ACDF reported fusion success in their ACDF arms.^{59,60,68,75-78,86,87,92-95,98,101} One trial (N=56) reported short-term fusion success in 89.3 percent of participants,¹⁰¹ seven RCTs (N=853) reported intermediate-term fusion success in 93.9 percent (range 89.1% to 98.2%) of participants^{59,68,75,78,92,98,101} and two RCTs (N=181) reported long-term fusion success in 96.5 percent (range 95.5% to 96.9%) of participants.^{60,95} One RCT reported successful fusion in the cervical arthroplasty arm as well, but this may be attributed to participant crossover after initial randomization.^{92,93}

3.9.3.1.2 Pain

3.9.3.1.2.1 Neck Pain

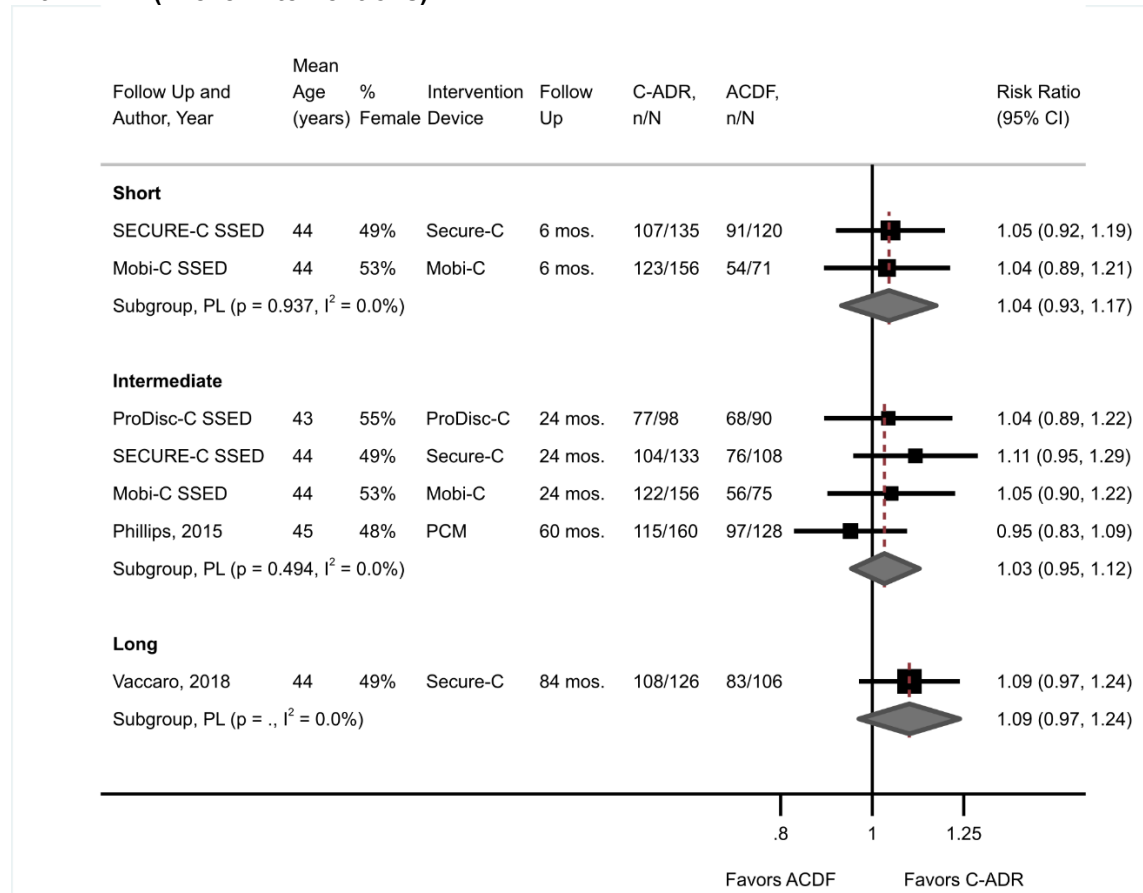
There was moderate-strength evidence of no differences between cervical arthroplasty and ACDF in neck pain or likelihood of success (response) for neck pain at short, intermediate, and long-term (SOE: Moderate).

Four RCTs (N=1,230) (in 5 publications)^{92,97,114,118,119} that compared single level cervical arthroplasty versus ACDF reported neck pain success (response) defined as postoperative ≥ 20 -point improvement on VAS. There were no differences in likelihood of neck pain success between cervical arthroplasty and ACDF at short term (2 RCTs, N=482, 79% vs. 75.0%, RR 1.04, 95% CI 0.93 to 1.17, $I^2=0\%$),^{114,119} intermediate term (4 RCTs, N=948, 76.4% vs. 74.1%, RR 1.03, 95% CI 0.95 to 1.12, $I^2=0\%$)^{92,114,118,119} or long term (1 RCT, N=232, 85.7% vs. 78.3%, 1.09, 95% CI 0.97 to 1.24)⁹⁷ (Figure 7). In one prospective NRSI IDE study using propensity-matched historical controls, more cervical arthroplasty participants had ≥ 20 -point improvement on VAS neck pain versus ACDF at 24 months (N=301, 91.2% vs. 77.9%, $p=0.013$).¹²⁰

One of the above trials reported neck pain success at 84 months using an alternative definition, a ≥ 10 -point improvement on VAS, and was not included in the meta-analysis at long term; there was no difference between cervical arthroplasty and ACDF using this criterion (N=191, 87.5% vs. 83.3%, RR 1.05, 95% CI 0.93 to 1.20).⁹⁵

3.9 Results, Key Question 8

Figure 7. Neck pain success (≥ 20 -point improvement on VAS): comparison of cervical arthroplasty with ACDF (1-level interventions)

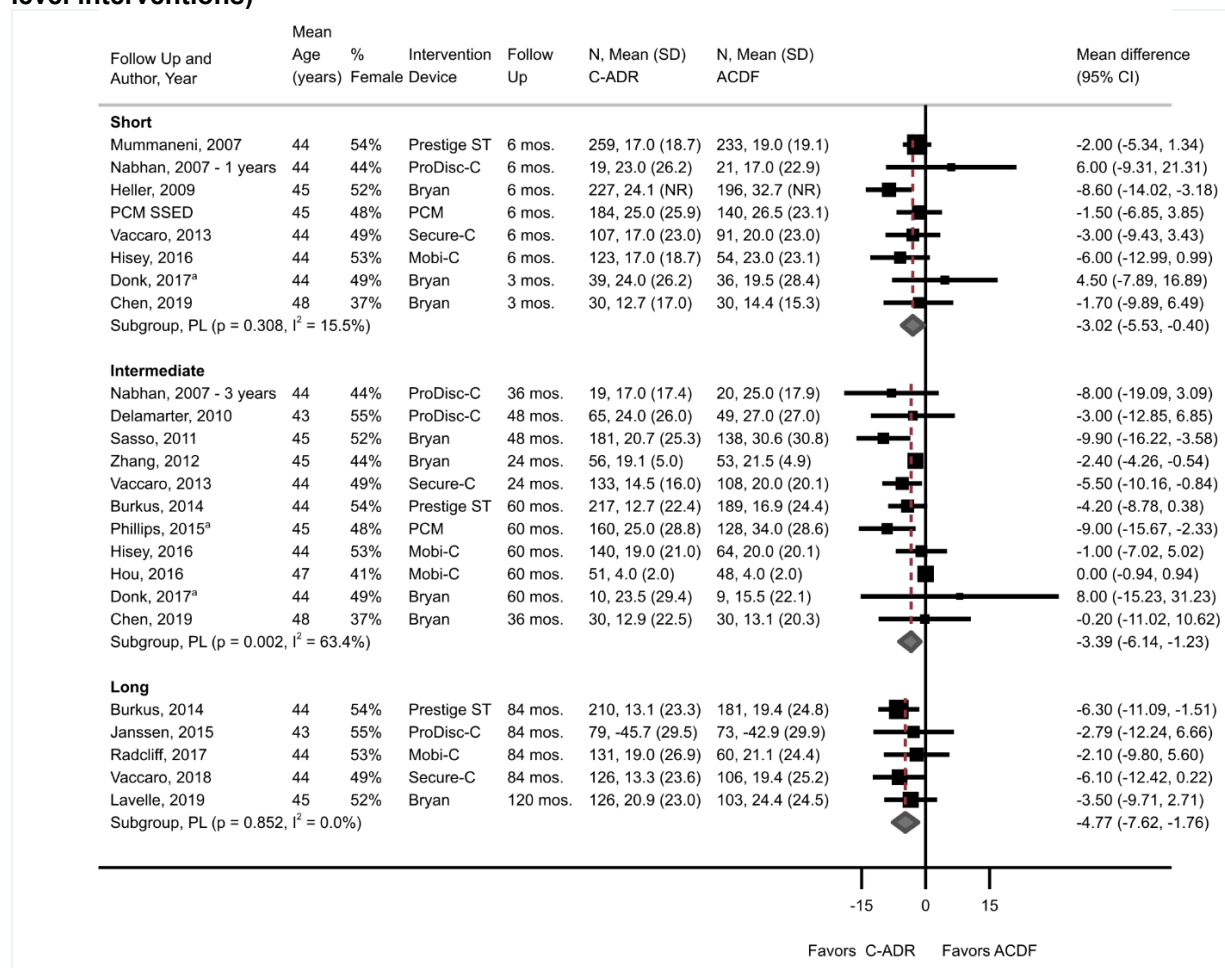


ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA); VAS = visual analogue scale.

Eleven RCTs (N=2,696) (in 19 publications)^{60,61,67,69,75,78,79,81,84,86,88,89,92,95-98,100,116} contributed to evaluation of mean differences in neck pain scores at various times. There were no differences between cervical arthroplasty and ACDF in VAS neck pain scores (0-100 scale) as estimates were below the threshold for a small effect at short term (8 RCTs, N=1,789, MD -3.02, 95% CI -5.53 to 0.40, I²=15.5%),^{61,69,75,78,86,89,98,116} intermediate term (11 RCTs, N=1,898, MD -3.39, 95% CI -6.14 to -1.23, I²=63.4%),^{60,61,67,69,78,79,88,92,96,98,100} and long term (5 RCTs, N=1,195, MD -4.77, 95% CI -7.62 to -1.72, I²=0%)^{60,81,84,95,97} (Figure 8). Exclusion of one, small (N=60) trial rated high risk of bias⁶¹ did not substantially change effect estimates but did slightly increase heterogeneity in the short term (7 RCTs, N=1,729, MD -3.11, 95% CI -5.92 to -0.15, I²=26.6%)^{69,75,78,86,89,98,116} and intermediate term (10 RCTs, N=1,838, MD -3.55, 95% CI -6.48 to -1.30, I²=67.1%).^{60,67,69,78,79,88,92,96,98,100} Exclusion of one trial⁶⁹ that did not specify if neck or arm pain was evaluated also did not substantially change effect estimates at short term (7 RCTs, N=1,714, MD -3.24, 95% CI -5.95 to -0.77, I²=12.2%)^{61,75,78,86,89,98,116} or intermediate term (10 RCTs, N=1,879, MD -3.51, 95% CI -6.35 to -1.33, I²=66.4%).^{60,61,67,78,79,88,92,96,98,100} Although funnel plot analysis and Egger's test (p=0.035) may suggest publication/small study bias for neck pain scores at intermediate term, most trials found no effect leading to less concern regarding publication bias (Appendix F, Figure F-4).

3.9 Results, Key Question 8

Figure 8. Neck pain VAS scores (0-100 scale): comparison of cervical arthroplasty with ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SD = standard deviation; SSED = Summary of Safety and Effectiveness Data (FDA); VAS = visual analogue scale.

^a Scores estimated from graphs in article.

3.9.3.1.2.2 Arm Pain

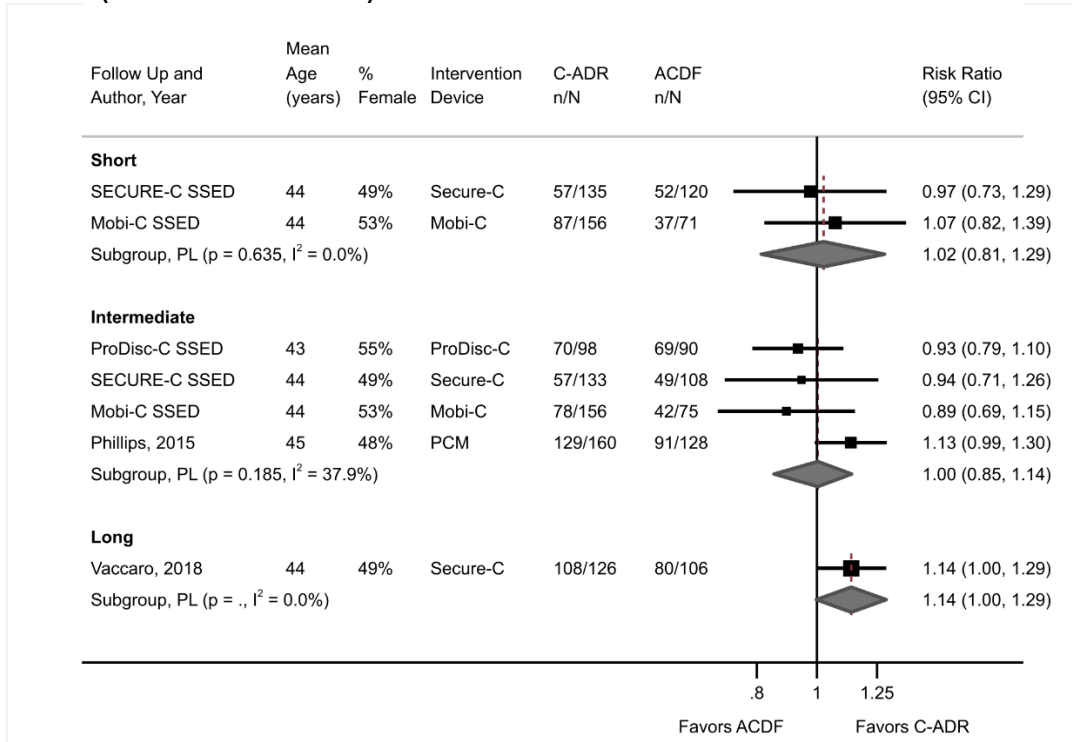
There was moderate-strength evidence of no differences between cervical arthroplasty and ACDF in arm pain or likelihood of success (response) for arm pain at short, intermediate, and long-term (SOE: Moderate).

Four RCTs (N=1,148) (in 5 publications)^{92,97,114,118,119} that compared cervical arthroplasty with ACDF for single level disease reported arm pain success (response) defined as postoperative ≥ 20 -point improvement on VAS (0–100). Some studies reported arm pain success in both arms. Conservative estimates, using the lower risk ratio for studies reporting VAS for both arms, revealed no difference in likelihood of arm pain success between cervical arthroplasty and ACDF at short term (2 RCTs, N=482, 49.5% vs. 46.6%, RR 1.02, 95% CI 0.81 to 1.29, I²=0%),^{114,119} intermediate term (4 RCTs, N=948, 61.1% vs. 62.6%, RR 1.0, 95% CI 0.85 to 1.14, I²=37.9%),^{92,114,118,119} or long term (1 RCT, N=232, 85.7% vs. 75.5%, RR 1.14, 95% CI 1.00 to 1.29, I²=0%)⁹⁷ (Figure 9). Estimates based on higher risk ratios for studies reporting VAS for both arms were similar and led to the same conclusion of no difference between cervical arthroplasty and ACDF for all time points. In one prospective NRSI IDE study using propensity-

3.9 Results, Key Question 8

matched historical controls, more cervical arthroplasty participants experience ≥ 20 -point improvement on VAS arm pain (worst side) versus ACDF at 24 months (N=301, 90.5% vs. 79.9%, p=0.001).¹²⁰

Figure 9. Arm pain success (≥ 20 -point improvement on VAS): comparison of cervical arthroplasty with ACDF (1-level interventions)

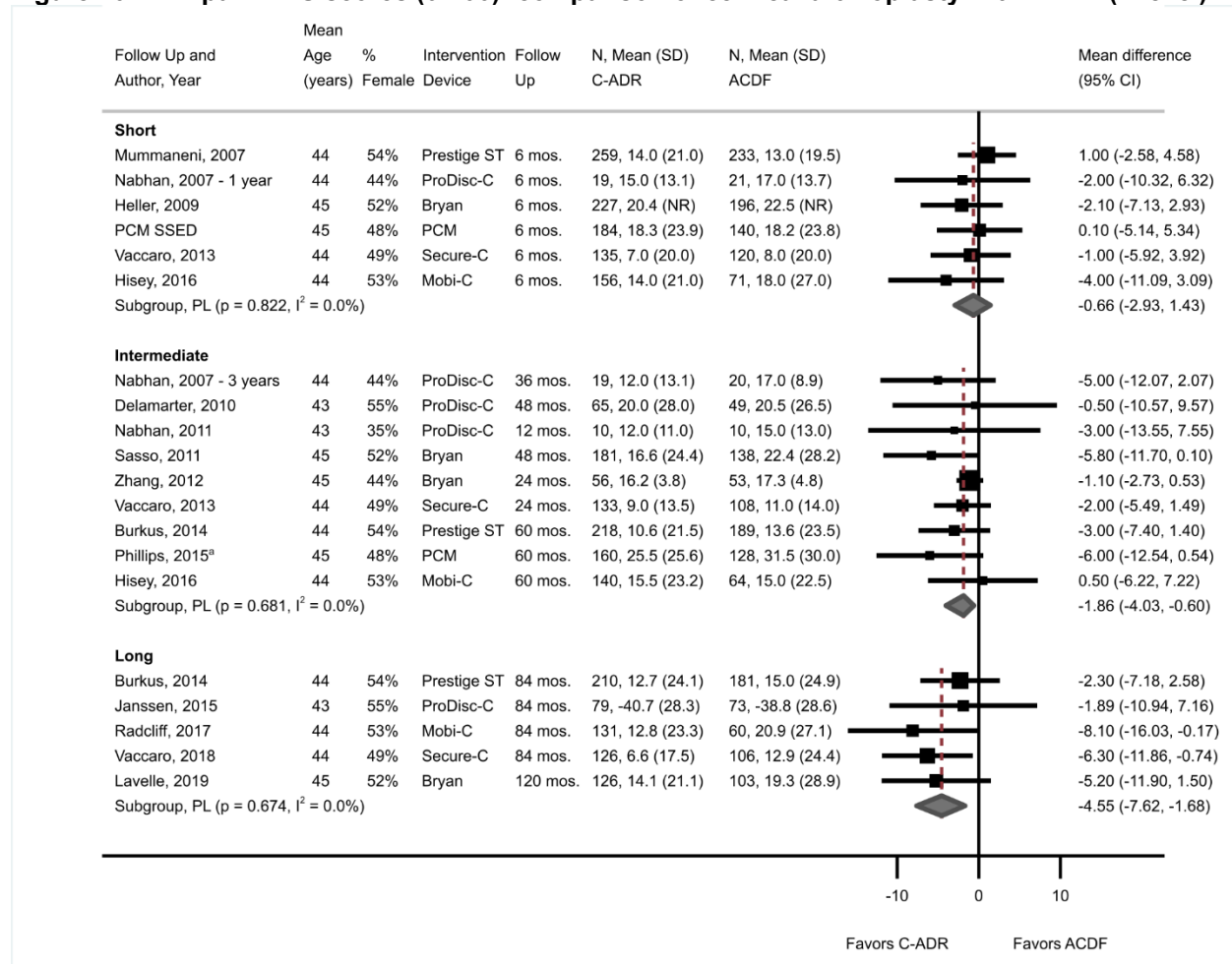


ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration: mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA); VAS = visual analogue scale.

Nine RCTs (N=2,460) (in 17 publications)^{60,67,75,78,81,84,86,88-90,92,95-98,100,116} assessed arm pain at various times. Three publications reported pain scores for both arms. Using a conservative estimate with the smaller effect estimate of the two arms, there was no difference between cervical arthroplasty and ACDF in VAS arm pain scores (0-100 scale) short term (6 RCTs, N=1,761, MD -0.66, 95% CI -2.93 to 1.43, $I^2=0\%$),^{75,78,86,89,98,116} intermediate term (9 RCTs, N=1,741, MD -1.86, 95% CI -4.03 to -0.60, $I^2=0\%$),^{60,67,78,88,90,92,96,98,100} or long term (5 RCTs, N=1,195, MD -4.55, 95% CI -7.62 to -1.68, $I^2=0\%$)^{60,81,84,95,97} (Figure 10). Exclusion of one small (N=20) trial rated high risk of bias⁹⁰ did not impact the effect size. Using the larger effect estimate when both arms were measured, slightly increased the estimate at short term but not the conclusion of no difference between treatments (MD -1.11, 95% CI -3.56 to 1.02); estimates at intermediate and long term were similar to the conservative estimates.

3.9 Results, Key Question 8

Figure 10. Arm pain VAS scores (0-100): comparison of cervical arthroplasty with ACDF (1-level)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; PL = profile likelihood; SD = standard deviation; SSED = Summary of Safety and Effectiveness Data (FDA); VAS = visual analogue scale.

^a Scores estimated from graphs in article.

3.9.3.1.3 Function

3.9.3.1.3.1 Neurologic Function

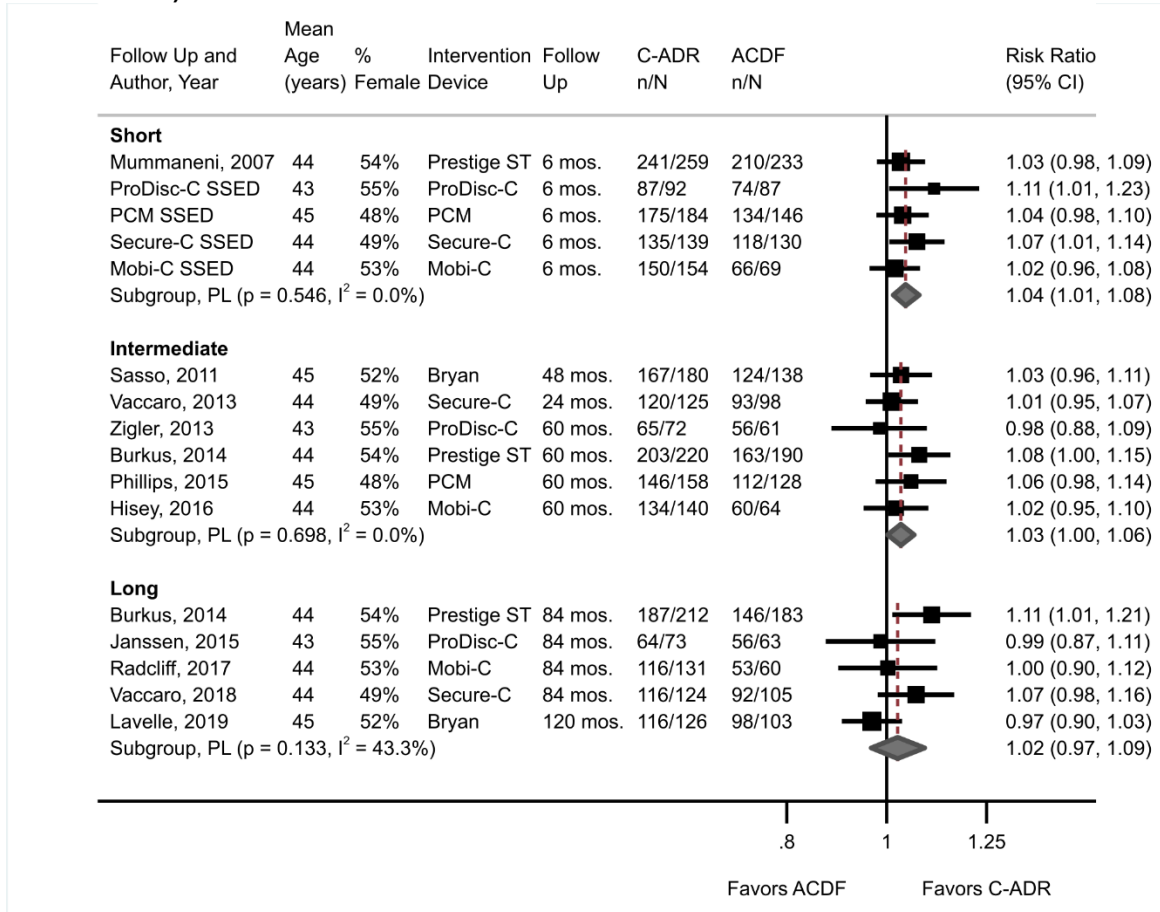
There was moderate-strength evidence of no differences between cervical arthroplasty and ACDF in neurologic function at short, intermediate, and long term (SOE: Moderate).

Six RCTs (N=2,271) (in 15 publications)^{60,78,81,84,86,92,95-98,102,114,116,118,119} that compared single-level cervical arthroplasty and ACDF reported neurologic success (response) defined as maintenance or improvement (compared with preoperative status) in all three of the following areas: motor function, sensory function and deep tendon reflexes. There were no differences between cervical arthroplasty and ACDF in the likelihood of neurological success short-term (5 RCTs, N=1,493, 95.2% vs. 90.5%, RR 1.04, 95% CI 1.01 to 1.08, I²=0%),^{86,114,116,118,119} intermediate term (6 RCTs, N=1,574, 93.3% vs. 89.5%, RR 1.03, 95% CI 1.00 to 1.06, I²=0%),^{60,78,92,96,98,102} or long term (5 RCTs, N=1,180, 89.9% vs. 86.6%, RR 1.02, 95% CI 0.97 to 1.09, I²=43.3%)^{60,81,84,95,97} (Figure 11). One prospective NRSI IDE study that used propensity matched ACDF historical controls reported neurological success, defined as maintenance or

3.9 Results, Key Question 8

improvement compared with baseline, was similar for cervical arthroplasty and ACDF at 24 months (N=314, 99.3% vs. 98.8%).¹²⁰

Figure 11. Neurological success: comparison of cervical arthroplasty with ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA); VAS = visual analogue scale.

Four RCTs (N=354), three rated high risk of bias^{63,91,101} and one low risk of bias,⁷⁹ reported JOA scores (0-17). There was no differences between cervical arthroplasty and ACDF in pooled analysis at intermediate term (4 RCTs, N=354, MD 0.60, 95% CI -0.007 to 0.97, I²=1.9%) or in one short-term trial rated high risk of bias (1 RCT, N=60, MD 0.25, 95% CI -0.25 to 0.75).⁶³

One trial reported the proportion of participants who had the same or an improved Nurick grade at 60 months compared with baseline; there were no differences (i.e., point estimate below the threshold for a small effect) between cervical arthroplasty and ACDF (N=285, 99.4% vs. 96.9%, RR 1.03, 95% CI 0.99 to 1.06).⁹³

3.9.3.1.3.2 General Function

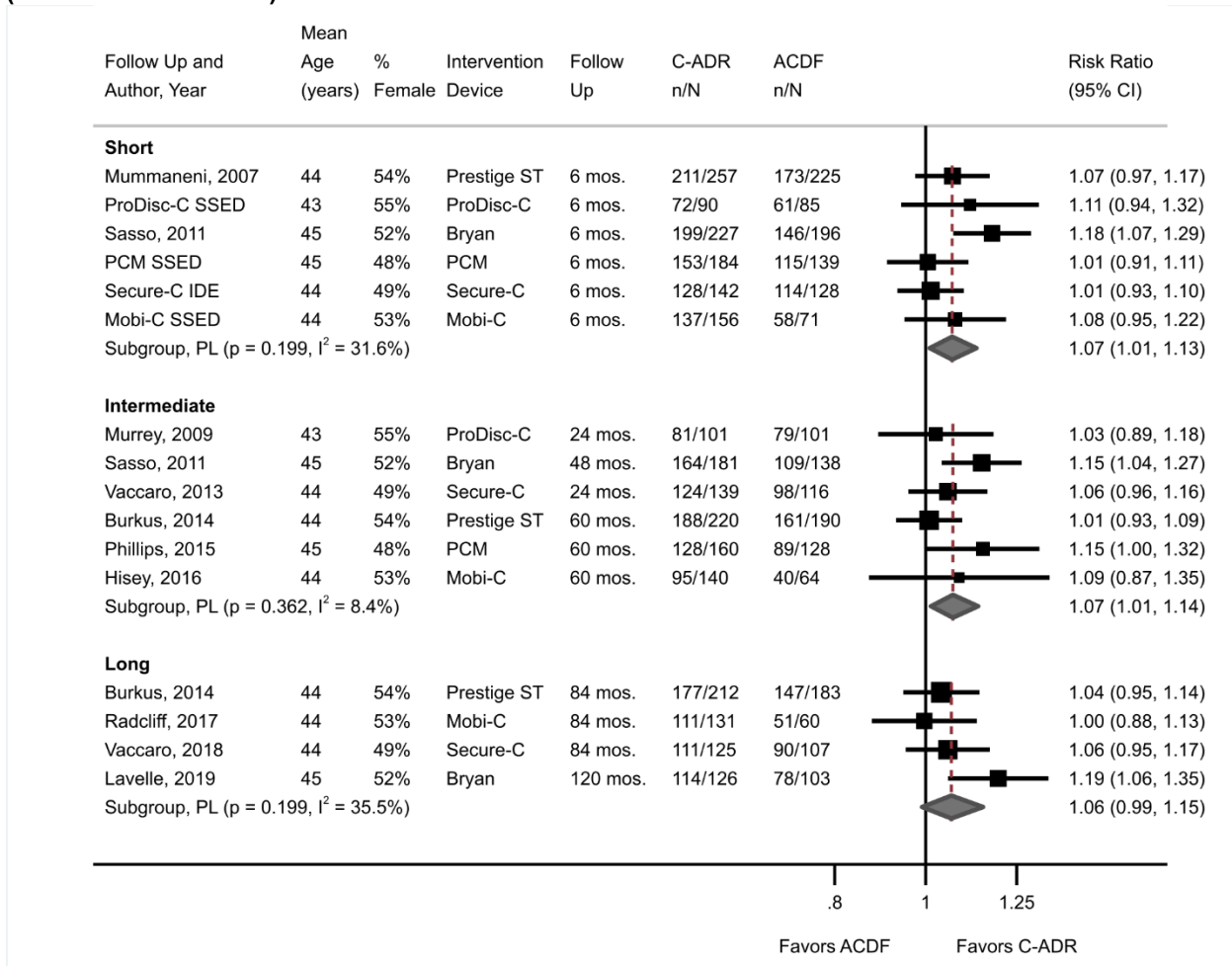
There was moderate-strength evidence of no differences between cervical arthroplasty and ACDF in general function at short, intermediate, and long term (SOE: Moderate).

3.9 Results, Key Question 8

3.9.3.1.3.2.1 NDI

Six RCTs (N=2,271) (in 14 publications)^{60,78,84,86,87,92,95-98,114,116,118,119} that compared cervical arthroplasty with ACDF for single-level disease reported NDI success (response) defined as postoperative NDI score improvement of ≥ 15 points from the baseline score (FDA definition). There were no differences between cervical arthroplasty and ACDF in the likelihood of NDI success short term (6 RCTs, N=1,900, 85.2% vs. 79.0%, RR 1.07, 95% CI 1.01 to 1.13, $I^2=31.6\%$),^{86,96,114,116,118,119} intermediate term (6 RCTs, N=1,678, 82.9% vs. 78.2%, RR 1.07, 95% CI 1.01 to 1.14, $I^2=8.4\%$),^{60,78,87,92,96,98} or long term (4 RCTs, N=1,047, 86.4% vs. 80.8%, RR 1.06, 95% CI 0.99 to 1.15, $I^2=35.5\%$)^{60,84,95,97} (Figure 12). In one prospective NRSI IDE study that used propensity-matched historical controls, there was no difference in NDI success (≥ 15 -point NDI improvement) following cervical arthroplasty versus ACDF at 24 months (N=301, 90.5% vs. 85.1%, $p=0.372$).¹²⁰

Figure 12. NDI success (≥ 15 -point improvement): comparison of cervical arthroplasty with ACDF (1-level interventions)



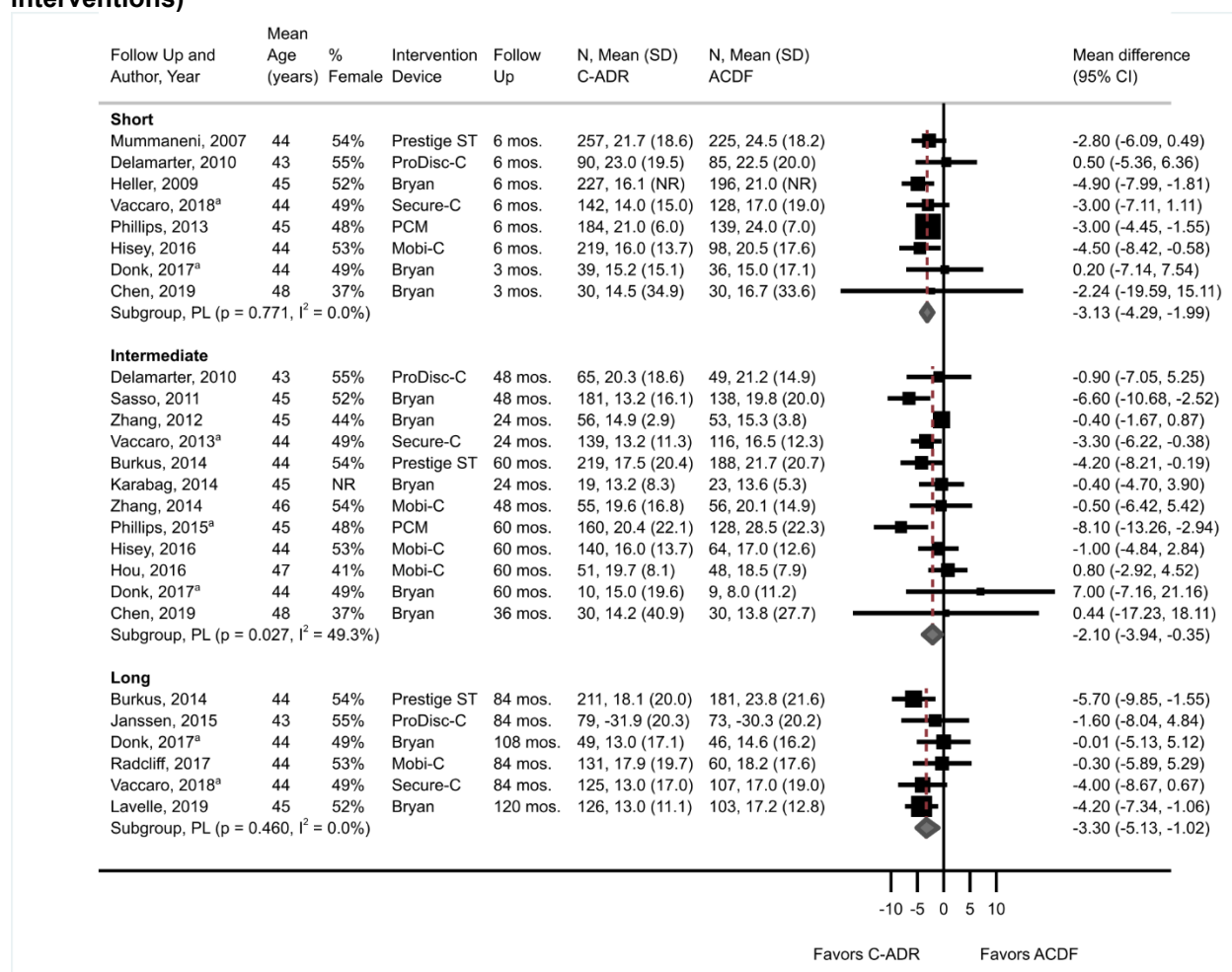
ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; NDI = Neck Disability Index; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA).

Twelve RCTs (N=2,800) (in 19 publications)^{60,61,67,69,75,78,79,81,82,84,86,92,93,95-98,100,101} that compared cervical arthroplasty with ACDF reported NDI scores (0-100 scale). There were no

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differences between cervical arthroplasty and ACDF in NDI scores as estimates were below the threshold for a small effect at short term (8 RCTs, N=2,125, MD -3.13, 95% CI -4.29 to -1.99, $I^2=0\%$),^{61,67,69,75,78,86,93,97} intermediate term (12 RCTs, N=2,027, MD -2.10, 95% CI -3.94 to -0.35, $I^2=49.3\%$),^{60,61,67,69,78,79,82,92,96,98,100,101} or long term (6 RCTs, N=1,291, MD -3.30, 95% CI -5.13 to -1.02, $I^2=0\%$)^{60,69,81,84,95,97} (Figure 13). Exclusion of trials rated high risk of bias^{61,82,101} had no impact on effect estimates or statistical heterogeneity in the short term (7 RCTs, N=2,065, MD -3.14, 95% CI -4.30 to -1.99, $I^2=0\%$)^{67,69,75,78,86,93,97} and slightly increased effect size and increased heterogeneity at intermediate term (9 RCTs, N=1,814, MD -2.45, 95% CI -4.70 to -0.35, $I^2=62.5\%$).^{60,67,69,78,79,92,96,98,100} Exclusion of a trial rated moderate risk of bias⁶⁹ with unclear sample sizes resulted in a small increase in effect size long term (5 RCT, N=1,288, MD -3.78, 95% CI -5.74 to -1.54).^{60,81,84,95,97} There was no indication of publication/small study bias for NDI scores at intermediate term based on funnel plot analysis (Egger's test, $p=0.416$) (Appendix F, Figure F-5).

Figure 13. NDI scores (0-100): comparison of cervical arthroplasty with ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; NDI = Neck Disability Index; PL = profile likelihood; SD = standard deviation.

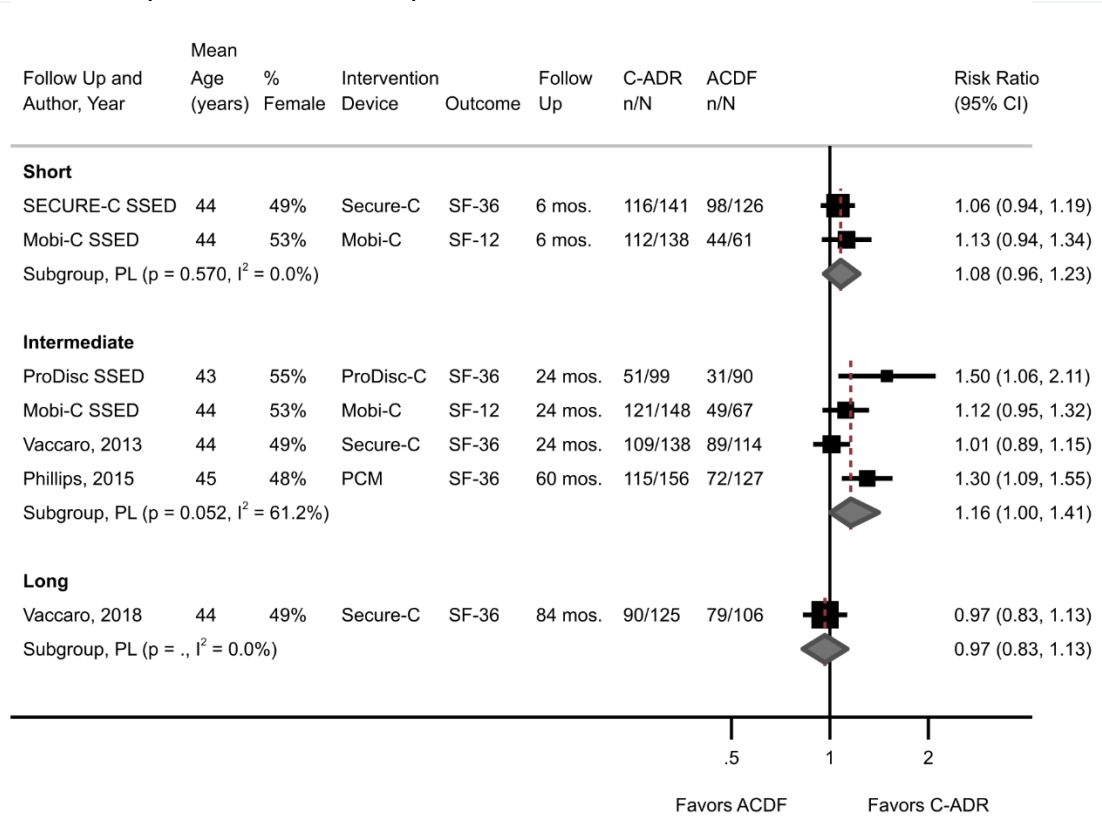
^a Scores estimated from graphs in article.

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3.9.3.1.3.2.2 SF-36 and SF-12 PCS and MCS

Four RCTs (N=1,148) (in 6 publications)^{92,97,98,114,118,119} that compared cervical arthroplasty with ACDF for single-level disease reported SF-36 and SF-12 PCS and MCS (0-100 scale). Success for these component scores was defined as postoperative score improvement of ≥ 15 points from baseline scores. The likelihood of PCS success was similar for cervical arthroplasty and ACDF short term (2 RCTs, N=466, 81.7% vs. 75.9%, RR 1.08, 95% CI 0.96 to 1.23, $I^2=0\%$),^{114,119} intermediate term (4 RCTs, N=939, RR 1.16, 95% CI 1.00 to 1.41, $I^2=61.2\%$),^{92,98,114,118} and long term (1 RCT, N=231, 72.0% vs. 74.5%, 0.97, 95% CI 0.83 to 1.13)⁹⁷ (Figure 14). Exclusion of one outlier trial¹¹⁸ at intermediate term resulted in a slightly attenuated effect estimate but did not reduce heterogeneity or change the conclusion (3 RCTs, N=750, RR 1.12, 95% CI 0.96 to 1.34, $I^2=59.8\%$).^{92,98,114} In one prospective NRSI IDE study using propensity-matched historical controls, more cervical arthroplasty participants maintained or improved PCS score versus ACDF at 24 months (N=301, 97.3% vs. 89.2%, $p=0.023$).¹²⁰ The likelihood of MCS success was also similar for cervical arthroplasty and ACDF at all time points: short term (2 RCTs, N=466, 49.1% vs. 42.8%, RR 1.13, 95% CI 0.86 to 1.50, $I^2=0\%$),^{114,119} intermediate term (4 RCTs, N=939, 47.3% vs. 48%, RR 0.97, 95% CI 0.80 to 1.16, $I^2=27.5\%$)^{92,98,114,118} and long term (1 RCT, N=231, 47.2% vs. 43.4%, RR 1.09, 95% CI 0.82 to 1.45)⁹⁷ (Figure 15). In the prospective NRSI IDE study, there was no difference in MCS maintenance or improvement between procedures at 24 months (N=301, 77.6% vs. 77.0%).¹²⁰

Figure 14. SF-36 or SF-12 PCS success (≥ 15 -point improvement): comparison of cervical arthroplasty with ACDF (1-level interventions)

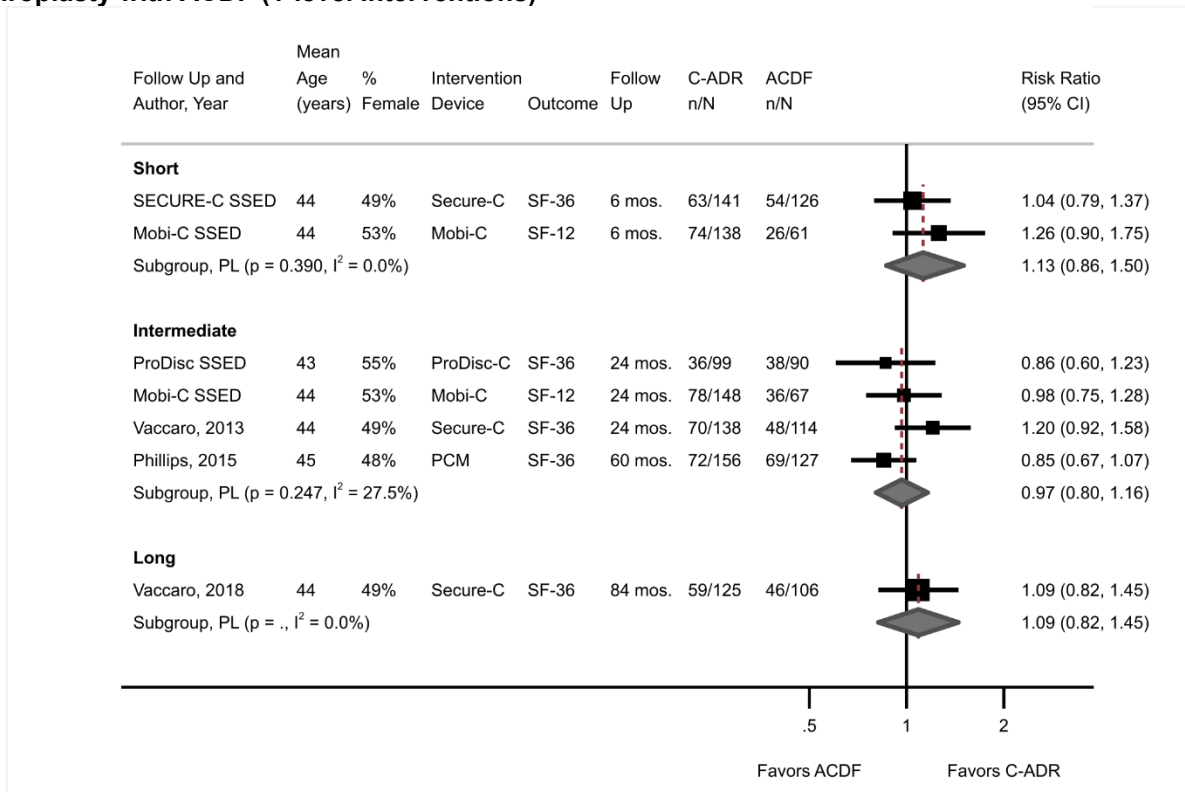


ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PCS = Physical Component Score; PL = profile

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likelihood; SF-12 = 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey; SSED = Summary of Safety and Effectiveness Data (FDA).

Figure 15. SF-36 or SF-12 MCS success (≥ 15 -point improvement): comparison of cervical arthroplasty with ACDF (1-level interventions)

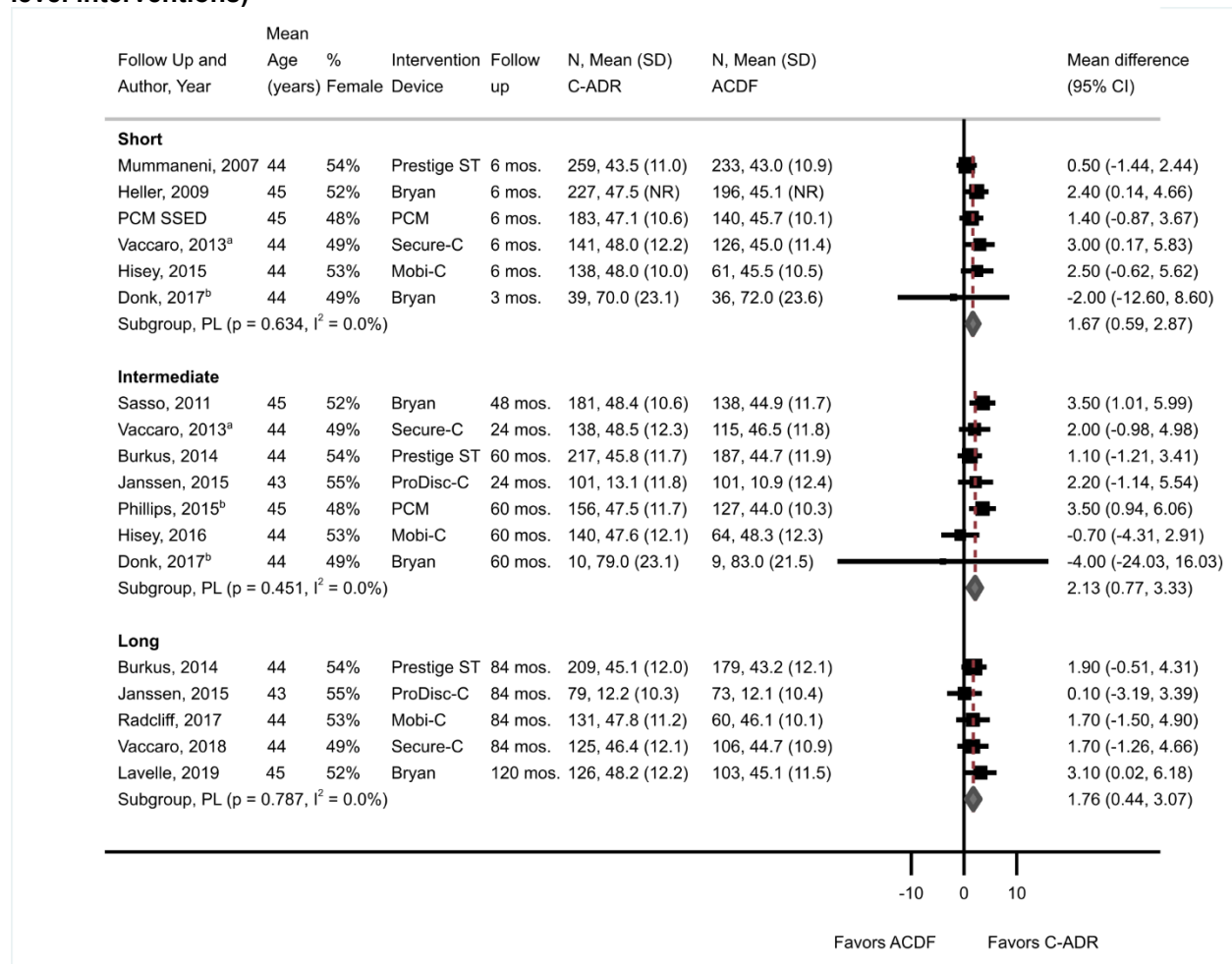


ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; MCS = Mental Component Score; mos. = months; PL = profile likelihood; SF-12 = 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey; SSED = Summary of Safety and Effectiveness Data (FDA).

Seven RCTs (N=2,368) (in 14 publications)^{60,69,75,77,78,81,84,86,92,95-98,116} that compared cervical arthroplasty with ACDF reported SF-36/12 PCS and MCS scores (0-100 scale). There were no differences between cervical arthroplasty and ACDF in PCS scores (Figure 16) as estimates were below the threshold for a small effect in the short-term (6 RCTs, N=1,779, MD 1.67, 95% CI 0.59 to 2.87, I²=0%), intermediate term (7 RCTs, N=1,684, MD 2.13, 95% CI 0.77 to 3.33, I²=0%), or long term (5 RCTs, N=1,191, MD 1.76, 95% CI 0.44 to 3.07, I²=0%). Similarly, there were no differences between cervical arthroplasty and ACDF in MCS scores (Figure 17) as estimates were below the threshold for a small effect in the short-term (6 RCTs, N=1,779, MD 1.14, 95% CI -0.14 to 2.17, I²=0%), intermediate term (7 RCTs, N=1,814, MD 0.83, 95% CI -0.75 to 2.41, I²=32.2%), and long term (3 RCTs, N=574, MD 0.64, 95% CI -1.47 to 2.82, I²=0%). Effect estimates for PCS and MCS did not differ following the exclusion of one trial with unclear samples sizes.⁶⁹ No studies were rated high risk of bias.

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Figure 16. SF-36 or SF-12 PCS scores (0-100): comparison of cervical arthroplasty with ACDF (1-level interventions)



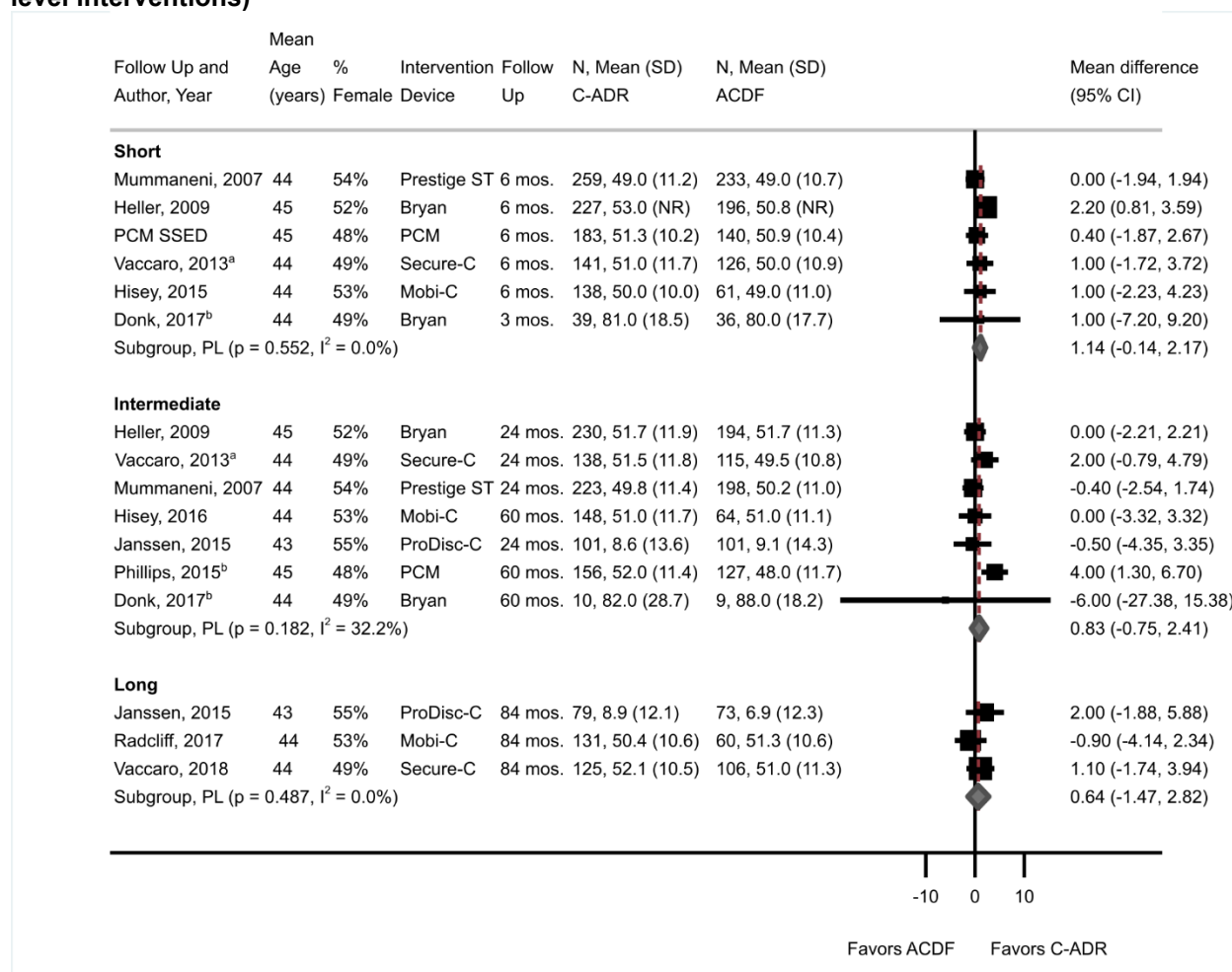
ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PCS = Physical Component Score; PL = profile likelihood; SF-12 = 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey; SD = standard deviation; SSED = Summary of Safety and Effectiveness Data (FDA).

^a n/N obtained from the SECURE-C SSED.

^b Scores estimated from graphs in article.

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Figure 17. SF-36 or SF-12 MCS scores (0-100): comparison of cervical arthroplasty with ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; MCS = Mental Component Score; mos. = months; PL = profile likelihood; SF-12 = 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey; SD = standard deviation; SSED = Summary of Safety and Effectiveness Data (FDA).

^a n/N obtained from the SECURE-C SSED.

^b Scores estimated from graphs in article.

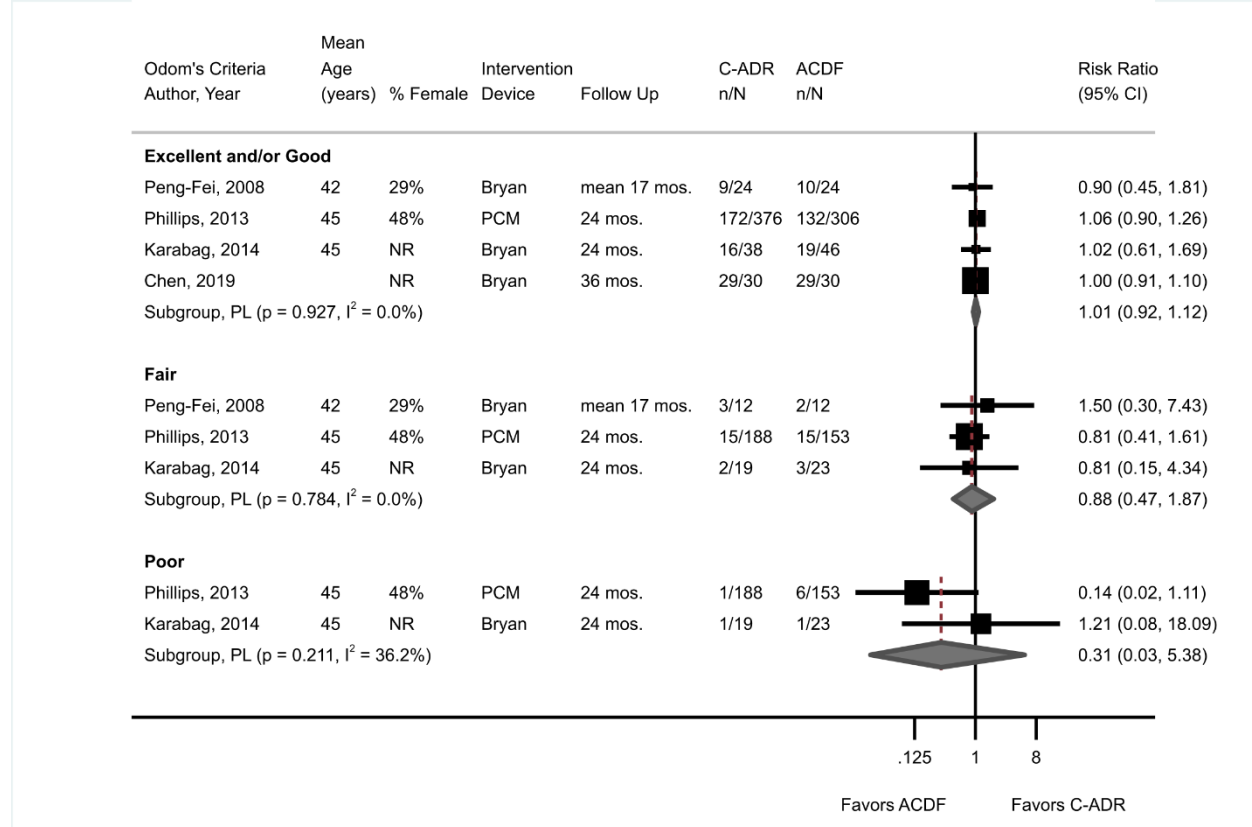
3.9.3.1.3.2.3 Odom's Criteria

Four RCTs (N=553)^{61,82,91,93} used Odom's criteria to categorize overall improvement as excellent (i.e., all pre-operative symptoms relieved, abnormal findings improved), good (i.e., minimal persistence of symptoms, abnormal findings unchanged or improved), fair (i.e., definite relief of some symptoms, others unchanged or slightly improved) or poor (i.e., symptoms and signs unchanged or exacerbated). There were no differences between single-level cervical arthroplasty and ACDF in the likelihood of having excellent or good results based on Odom's criteria (4 RCTs, N=847, 48.3% vs. 46.8%, RR 1.01, 95% CI 0.92 to 1.12, I²=0%) at intermediate term.^{61,82,91,93} However, three of the RCTs (all small) were rated high risk of bias,^{61,82,91} while the one large RCT was rated moderate risk of bias.⁹³ Based on the highest quality trial, there was no difference between procedures in the likelihood of having excellent or good improvement (1 RCT, N=682, 45.7% vs. 43.1%)⁹³ (Figure 18). In one prospective NRSI IDE study using propensity-matched historical controls, there was no difference between cervical

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arthroplasty and ACDF in the likelihood of having excellent or good results using Odom’s criteria at 24 months (N=301, 90.5% vs. 79.9%).¹²⁰

Figure 18. Odom’s criteria: comparison of cervical arthroplasty with ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; mos. = months; PL = profile likelihood.

3.9.3.1.3.3 Overall Success (Composite)

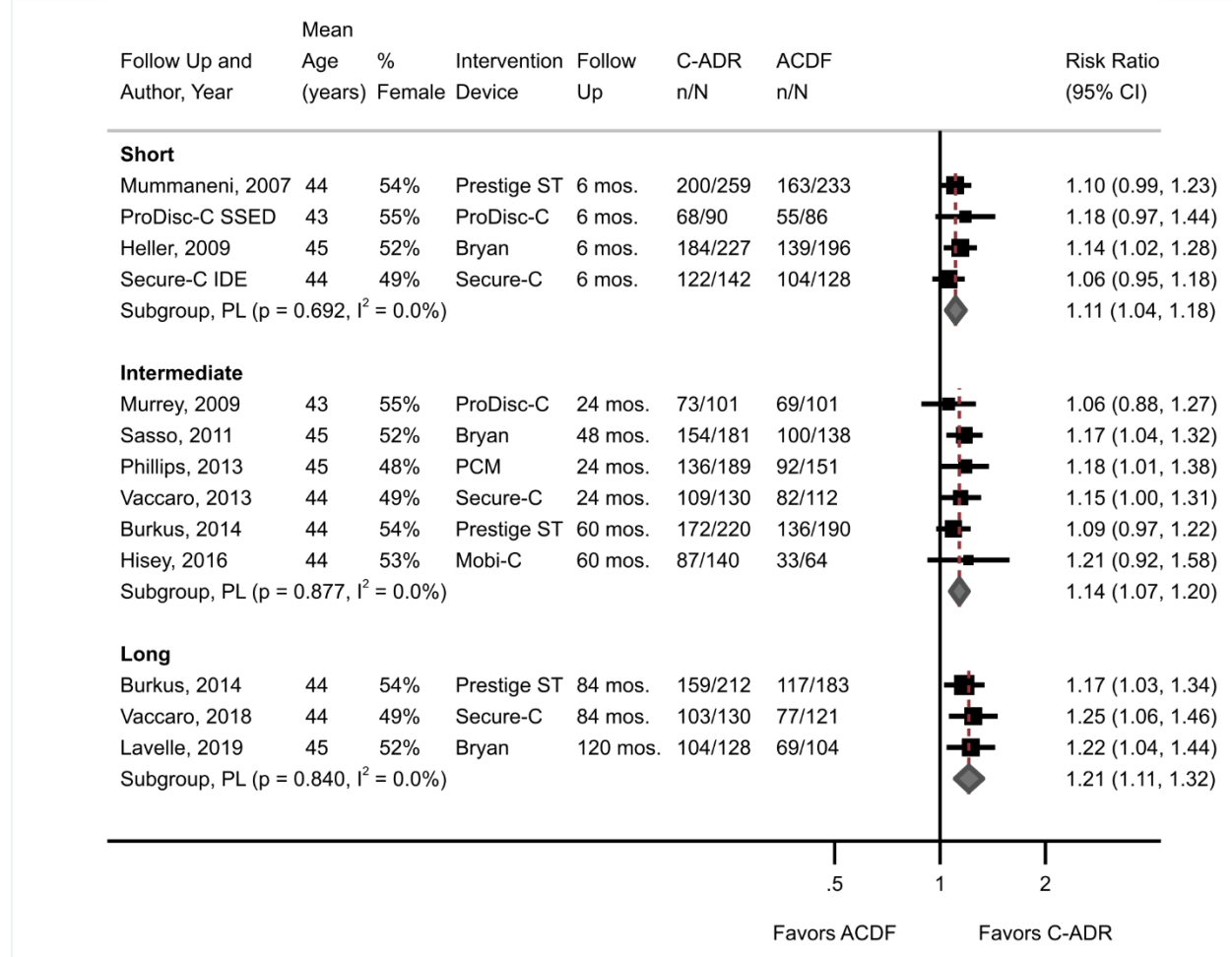
The FDA IDE trials were required to report overall success, a composite outcome for six RCTs (N=2,271) (in 11 publications)^{60,75,78,84,86,87,93,96,98,118,119} that included a threshold of ≥ 15 -point NDI improvement (0-50 scale) from baseline, improvement or maintenance of neurologic status, no serious adverse events and no additional surgical procedures that might be considered “failure” (e.g., removal, revision, supplemental fixation). In participants with single-level interventions, effect estimates were below the threshold for a small effect and classified as no difference in overall success comparing cervical arthroplasty with ACDF in the short term (4 RCTs, N=1,361, 79.9% vs. 71.7%, RR 1.11, 95% CI 1.04 to 1.18, $I^2=0\%$)^{75,86,118,119} and intermediate term (6 RCTs, N=1,717, 76.1% vs. 67.7%, RR 1.14, 95% CI 1.07 to 1.20, $I^2=0\%$),^{60,78,87,93,96,98} but a slightly increased likelihood of overall success favoring cervical arthroplasty was seen long term (3 RCTs, N=878, 76.1% vs. 67.7%, RR 1.21, 95% CI 1.11 to 1.32, $I^2=0\%$)^{60,84,98} (Figure 19). In one prospective NRSI IDE study using propensity-matched historical controls, there was no difference between cervical arthroplasty and ACDF in overall response (same definition as in RCTs) at 24 months (N=301, 86.8% vs. 79.3%, $p=0.265$).¹²⁰

One of the above trials reported overall success at 84 months using a different criterion for NDI (improvement in NDI score ≥ 30 points if preoperative score ≥ 60 or improvement of $\geq 50\%$ if preoperative score < 60) and included an additional requirement for radiographic success, and

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was not included in the meta-analysis at long term; there was no difference between cervical arthroplasty and ACDF using this criteria (N=166, 55.2% vs. 50.0%, RR 1.10, 95% CI 0.80 to 1.52).⁹⁵

Figure 19. Overall success: comparison of cervical arthroplasty with ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA).

3.9.3.1.3.4 Quality of Life

None of the included studies reported on quality-of-life measures.

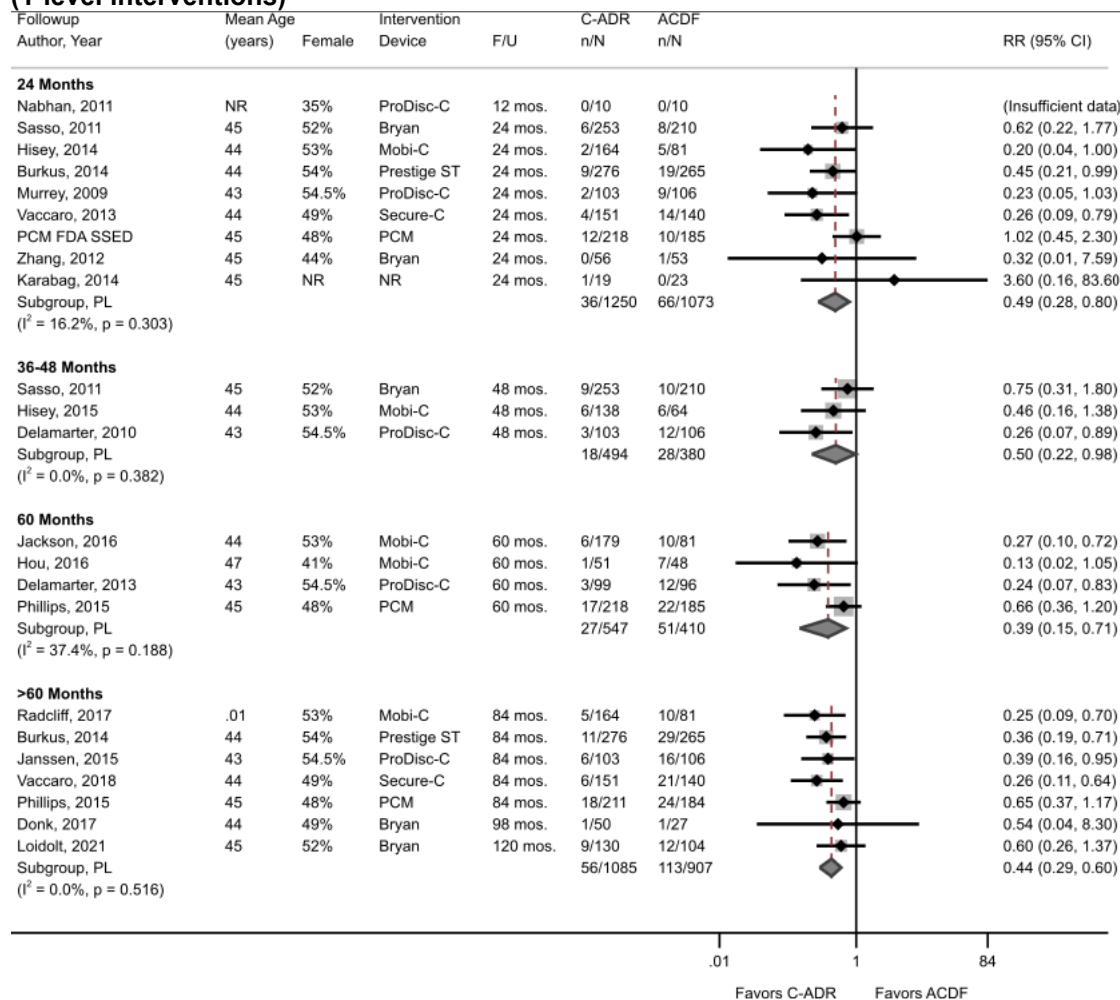
3.9.3.1.3.5 Reoperation and Subsequent Surgery

There was high-strength evidence that cervical arthroplasty was associated with substantially lower likelihood of reoperation that included the index level versus ACDF (SOE: High). Rates of reoperation for ACDF at the index level may be influenced by the need to remove an existing plate to treat adjacent segment disease (ASD), rather than the indication for reoperation being driven by an issue at the index procedure. This may artificially inflate the reported reoperation rate at the index procedure level for ACDF when compared with cervical arthroplasty. Studies were not consistently clear in the indication for reoperation. The clinical relevance of removing the plate as a part of a procedure addressing ASD is minimal.

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Reoperation including any additional procedure at the index level was substantially less frequent with cervical arthroplasty versus ACDF for single-level disease at all time points reported in RCTs including short term up to 24 months (9 RCTs, N=2,323, 2.9% vs. 6.2%, RR 0.49, 95% CI 0.28 to 0.80, $I^2=16.2%$)^{60,76,82,87,90,96,98,100,116} and long term from 84 to 120 months (7 RCTs, N=1,992, 5.2% vs. 12.5%, RR 0.44, 95% CI 0.29 to 0.60, $I^2=0%$)^{60,69,81,85,92,95,97} (Figure 20).

Figure 20. Reoperation involving the index level: comparison of cervical arthroplasty with ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA).

One prospective NRSI IDE study of cervical arthroplasty using historical ACDF controls found no difference in index-level reoperation up to 24 months (N=349, 1.9% vs. 4.8%, RR 0.39, 95% CI 0.11 to 1.43).¹²⁰

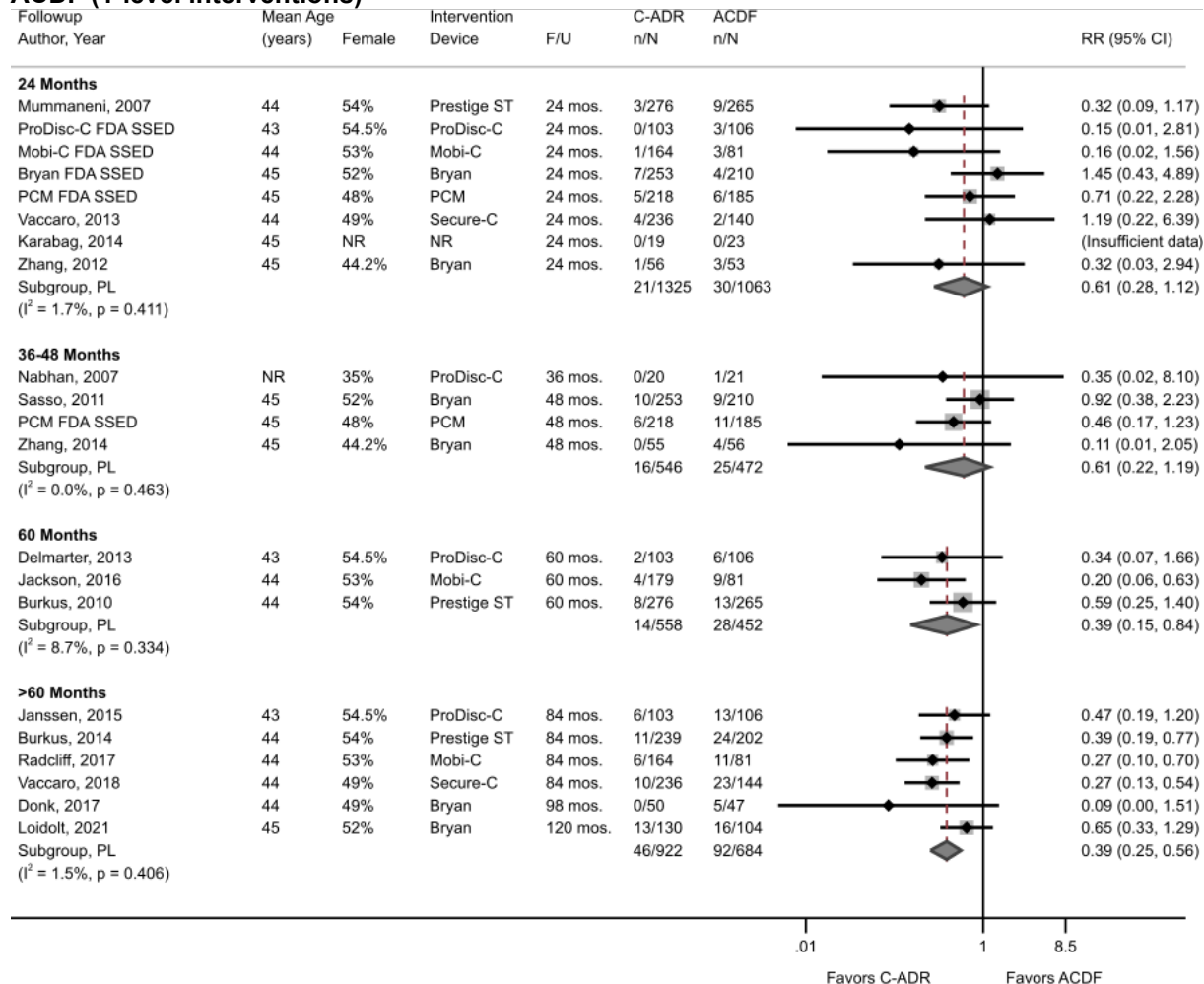
Reoperation across two NRSIs was less common than that reported in RCTs. No difference in 30-day reoperation was seen in one NRSI (1.2% vs. 0.4%, adjusted OR 0.60, 95% CI 0.14 to 2.56).¹⁰⁹ Another NRSI reported that reoperation was less common following cervical arthroplasty within 90 days of index surgery compared with ACDF (2.04% vs. 3.35%, adjusted

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OR 0.63, 95% CI 0.44 to 0.92) but no difference between cervical arthroplasty and ACDF longer-term up to 5 years (adjusted hazard ratio 0.86, 95% CI 0.60 to 1.23).¹⁰⁸ While overall reoperation rates were lower in these database NRSIs, it is possible the RCTs, particularly IDE trials may provide more accurate detail regarding specific indications.

Subsequent surgery rates at adjacent levels were similar between cervical arthroplasty and ACDF at up to 24 months^{82,86,98,100,114-116,118} and between 36 and 48 months (including after exclusion of one trial rated high risk of bias¹⁰¹)^{89,96,101,116} but was substantially less likely with cervical arthroplasty versus ACDF at 60 months (3 RCTs, N=1,010, 2.5% vs. 6.2%, RR 0.39, 95% CI 0.15 to 0.84, I²=8.7%)^{59,68,80} and at the longest followups from 84 to 120 months (6 RCTs, N=1,606, 5.0% vs. 13.5%, RR 0.39, 95% CI 0.25 to 0.56, I²=1.5%).^{60,69,81,85,95,97} However, estimates were somewhat imprecise (Figure 21). Also, across trials, indications for operation at adjacent levels were not consistently described.

Figure 21. Subsequent surgery at adjacent levels: comparison of cervical arthroplasty versus ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA).

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3.9.3.1.3.6 Harms

All 15 RCTs that evaluated cervical arthroplasty and ACDF for single-level disease provided information on adverse events and harms up to 120 months followup.^{60,61,69,76,79,82,87,89,90,92,96,98,100,101,116} Information on harms from four NRSIs was used to complement that from RCTs.^{106,108,109,120}

3.9.3.1.3.6.1 Neurologic Deficit

There was low-strength evidence of no differences in the likelihood of neurological events or deficits between cervical arthroplasty and ACDF in the short, intermediate, or long term (SOE: Low).

Reporting of neurological events varied across RCT publications. Three publications assessed events from the Bryan IDE trial at different times;^{58,85,96} one IDE trial evaluated Mobi-C.⁹⁵ One trial⁵⁸ described specific, observed neurological events as acute neurological changes, while other trials used various general terms to describe neurologic events (e.g., new deficit, neurological failure, neurological adverse event). The timing of events following surgery was also not clearly reported. Thus, reported proportions of participants who experienced neurological events varied substantially across RCTs, however there were no differences between cervical arthroplasty and ACDF at 0 to 24 months (3.3% vs. 3.2%),⁵⁸ between 24 and 48 months (0% vs. 1.0%, WHO grade 3 or 4),⁹⁶ up to 84 months (11.4 % vs. 11.5%),⁹⁵ or up to 120 months (any: 43.1% vs. 43.8%; WHO grade 3 or 4: 4.5% vs. 6.9%).⁸⁵ One prospective NRSI IDE study of cervical arthroplasty that used propensity-matched historical ACDF controls reported no differences in serious device- or procedure-related neurological adverse events between cervical arthroplasty and ACDF (1.3% vs. 1.6%) through 24 months.¹²⁰ The same trial study also reported fewer cervical arthroplasty participants experienced neurological decrease from baseline versus ACDF (6.7% vs. 12.8%, RR 0.52, 95% CI 0.25 to 1.07) but results were imprecise.

3.9.3.1.3.6.2 Mortality

There was inadequate evidence to draw conclusions on the likelihood of death in participants undergoing cervical arthroplasty versus ACDF (SOE: Insufficient).

Death was uncommon (<3%) in RCTs and NRSIs, with no reported differences between cervical arthroplasty and ACDF. Across RCTs, no deaths were directly attributed to either procedure, however cause of death was not reported in many trials. For cervical arthroplasty from 0 to 24 months, three of the four deaths were attributed to myocardial infarction or cardiac arrest in one trial;⁶⁰ the cause of the fourth death was not reported in another trial.⁹⁸ No deaths were observed in one trial.⁷⁶ At followup from 0 to 36 months, one cervical arthroplasty participant died of a severe subarachnoid hemorrhage at 6 weeks (relationship to procedures was not stated)⁸⁹ and one death in the ACDF group attributed to a motor vehicle accident was observed in another trial.⁵⁸ There was no difference in mortality between procedures at 84 months (1 RCT, N=541, 0.9% vs. 2.2%, RR 0.38, 95% CI 0.08 to 1.96)⁶⁰ or at 120 months (1 RCT, N=232, 1.4% vs. 2.4%, RR 0.54, 95% CI 0.09 to 3.18),⁸⁵ however estimates were imprecise. Findings from one large administrative data NRSI¹⁰⁸ reinforce that death was rare for cervical arthroplasty (0%) and ACDF (0.18%) and that there was no difference between procedures in the likelihood of mortality. One death occurred in the cervical arthroplasty group in one NRSI IDE study using historical controls up to 24 months¹²⁰ (Appendix C).

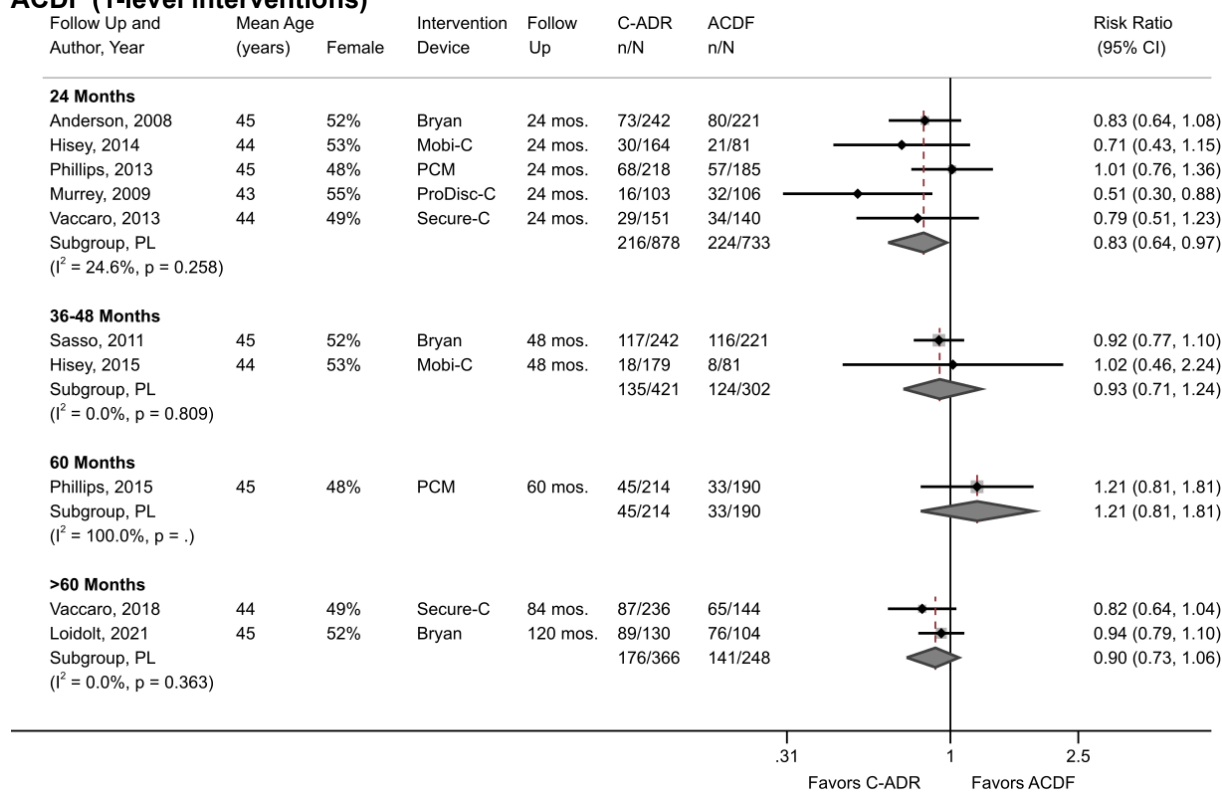
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3.9.3.1.3.6.3 Serious Adverse Events

There was low-strength evidence that cervical arthroplasty was associated with a slightly lower likelihood of any serious adverse event in the short term versus ACDF (SOE: Low); there was also low-strength of no differences in the likelihood of experiencing a serious adverse events at greater than 24 months (SOE: Low).

Serious adverse event definitions and types of events varied across RCTs, but often included events that were life threatening, required medical intervention, or resulted in a permanent disability or death. Timing of events was not reported. Events related to participant factors such as comorbidities (e.g., underlying cardiovascular disease) would likely not be different between procedures. Cervical arthroplasty was associated with a slightly lower likelihood of experiencing a serious adverse event up to 24 months across IDE trials (5 RCTs, N=1,611, 24.6% vs. 30.6%, RR 0.83, 95% CI 0.64 to 0.97, $I^2=24.6\%$)^{58,76,87,93,98} compared with ACDF, however across fewer trials at other times, no differences between procedures was seen (Figure 22). No difference in the likelihood of experiencing a serious adverse events was seen between cervical arthroplasty and ACDF (N=349, 9.4% vs. 14.8%, RR 1.97, 95% CI 0.88 to 4.37) in one NRSI IDE study using historical controls up to 24 months.

Figure 22. Any serious adverse events (author defined): comparison of cervical arthroplasty with ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; mos. = months; PL = profile likelihood.

Dysphagia was reported by six RCTs (N=1,965) (in 8 publications),^{58,60,68,69,76,81,85,98} but the severity was unclear in most cases. One trial (N=463) reported no cases of WHO grade 3 or 4 dysphagia in any participant through 24 months followup.⁵⁸

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NRSIs based on administrative data suggest that serious adverse events are rare and not different between cervical arthroplasty and ACDF. Thrombotic event rates (DVT and/or pulmonary embolism) were similar between cervical arthroplasty (range 0.07% to 0.19%) and ACDF (0.10% to 0.11%) as reported by two large NRSIs.^{106,108} One NRSI¹⁰⁸ reported rates of vertebral artery injury and dural tear of less than 1 percent in for each procedure. One NRSI reported low risk of dysphagia (0% vs. 0.13%)¹⁰⁹ but did not report dysphagia severity. Dysphagia was more common in cervical arthroplasty participants versus ACDF participants (9.4% vs. 6.3%) but severity was not described in one prospective NRSI IDE study using historical ACDF controls.¹²⁰

3.9.3.1.3.6.4 Heterotopic Ossification

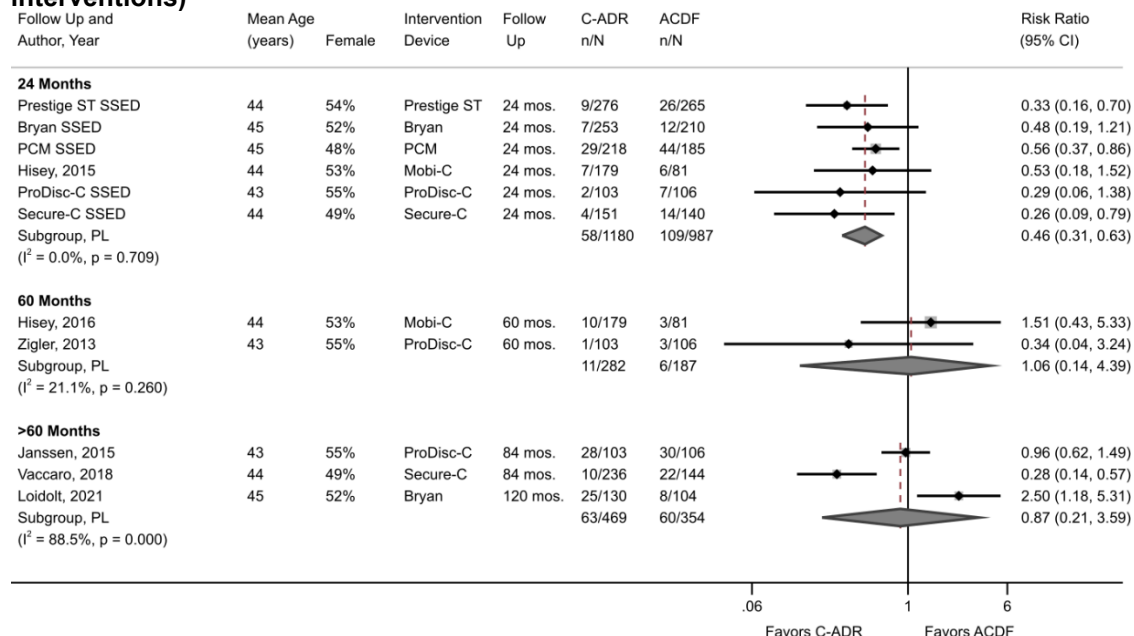
Grade 3 or 4 heterotopic ossification (HO), considered clinically relevant HO by most of the trials, may be of concern with cervical arthroplasty. Across five RCTs (N=525 for cervical arthroplasty arm, range 30 to 182), 9.5 percent of participants (range, 1.8% to 12.8%) developed Grade 3 or 4 HO across 24 to 84 months followup.^{61,92,95,97,100} In addition, one FDA IDE NRSI (n=150 in cervical arthroplasty arm) reported rates of grade 3 or 4 HO at 24 months (11.3%; 0.7%, grade 4).¹⁰⁵ Rates of Grade 1 or 2 (or unclear grades) of HO ranged from 0 to 32.7 percent across seven trials (N range for cervical arthroplasty arms, 51 to 201) over 12 to 84 months followup^{60,61,76,79,81,100,101} and was 44 percent at 24 months in the NRSI.¹⁰⁵

3.9.3.1.3.6.5 Device-Related Adverse Events

Device-related adverse event definitions, types of events and adjudication varied across RCTs. Some trials included a range of events such as adjacent-level degenerative joint changes, headache as well as neurological events. Some device-related events may only occur with cervical arthroplasty, others may only occur with ACDF (e.g., nonunion). Some events may not be persistent or serious (e.g., superficial wound infection, dysphagia). Cervical arthroplasty was associated with substantially lower likelihood of device-related events at 24 months (6 RCTs, N=2,167, 4.9% vs. 11%, RR 0.46, 95% CI 0.31 to 0.63, I²=0%).^{77,115-119} No difference was seen across two trials at 60 months,^{78,102} but results across three trials at >60 months^{81,85,97} were inconsistent (Figure 23).

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Figure 23. Device-related adverse events: comparison of cervical arthroplasty with ACDF (1-level interventions)



ACDF = anterior cervical discectomy and fusion; CI = confidence interval; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA).

3.9.3.1.3.6.6 Differential Effectiveness (Heterogeneity of Treatment Effect [HTE])

None of the included trials that compared single-level cervical arthroplasty and ACDF interventions reported differential effectiveness based on patient or other characteristics.

3.9.3.2 Two-Level Cervical Arthroplasty Versus ACDF

Four RCTs (N=872) (in 11 publications)^{63,65,66,71-73,80,83,94,95,99} compared two-level cervical arthroplasty and ACDF, including two FDA IDE trials (in 9 publications)^{65,66,71-73,80,83,94,95} and two non-IDE trials.^{63,99} One FDA IDE NRSI¹⁰⁴ compared a novel polyetheretherketone (PEEK)-on-ceramic cervical arthroplasty with propensity score-matched historical ACDF controls (structural allograft and plate) from a multicenter RCT initiated in the mid-2000s that was not referenced.

3.9.3.2.1 Fusion

Two RCTs (N=727) (across 4 publications) that compared two-level cervical arthroplasty and ACDF procedures reported fusion success in their ACDF arms.^{71,83,94,95} No trials reported short-term fusion success. Two RCTs (N=243) reported intermediate-term fusion success in 92.5 percent (range: 90.5% to 94.0%) of participants.^{83,94} Two RCTs (N=196) reported long-term fusion success in 92.6 percent (range: 90.9% to 93.8%) of participants.^{71,95} One IDE NRSI¹⁰⁴ comparing a novel cervical arthroplasty versus historical ACDF controls reported pseudarthrosis in 6.5 percent of the ACDF group.

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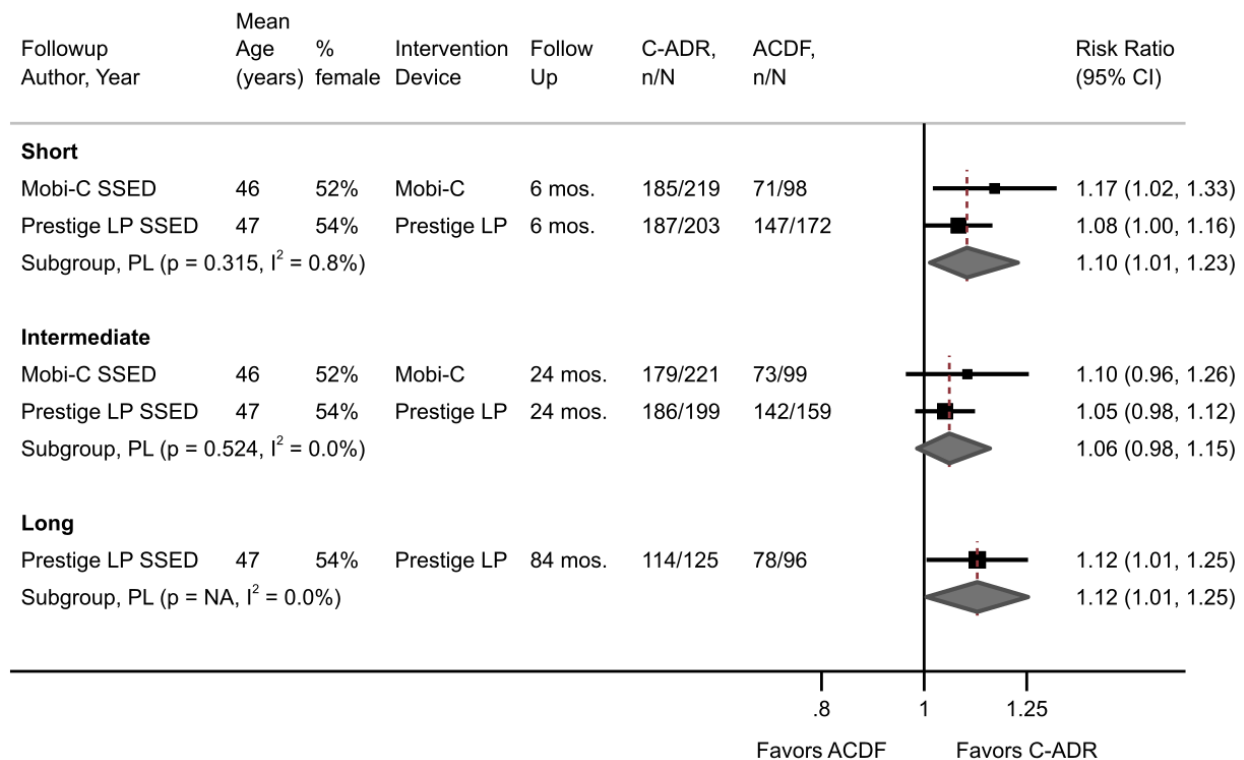
3.9.3.2.2 Pain

3.9.3.2.2.1 Neck Pain

There was moderate-strength evidence of no difference between cervical arthroplasty and ACDF on neck pain (SOE: Moderate).

Two RCTs (N=727)^{121,122} that compared cervical arthroplasty with ACDF reported neck pain success (response) defined as postoperative ≥ 20 -point improvement on VAS (0-100 scale). In participants having two-level interventions there were no differences in likelihood of neck pain success between cervical arthroplasty and ACDF in the short term (2 RCTs, N=692, 88% vs. 80.7%, RR 1.10, 95% CI 1.01 to 1.23, $I^2=0.8\%$),^{121,122} intermediate term (2 RCTs, N=678, 86.9% vs. 83.3%, RR 1.06, 95% CI 0.98 to 1.15, $I^2=0\%$),^{121,122} and long term (1 RCT, N=221, 91.2% vs. 81.3%, RR 1.12, 95% CI 1.01 to 1.25)¹²² as estimates were below the threshold for a small effect (Figure 24). There was also no difference long term between cervical arthroplasty and ACDF in the trial using a threshold of ≥ 10 -point improvement for neck pain success that was not included in the meta-analysis (1 RCT, N=269, 86% vs 77.7%, RR 1.11, 95% CI 0.97 to 1.32).⁹⁵

Figure 24. Neck pain success (≥ 20 -point improvement on VAS): comparison of cervical arthroplasty with ACDF (2-level interventions)



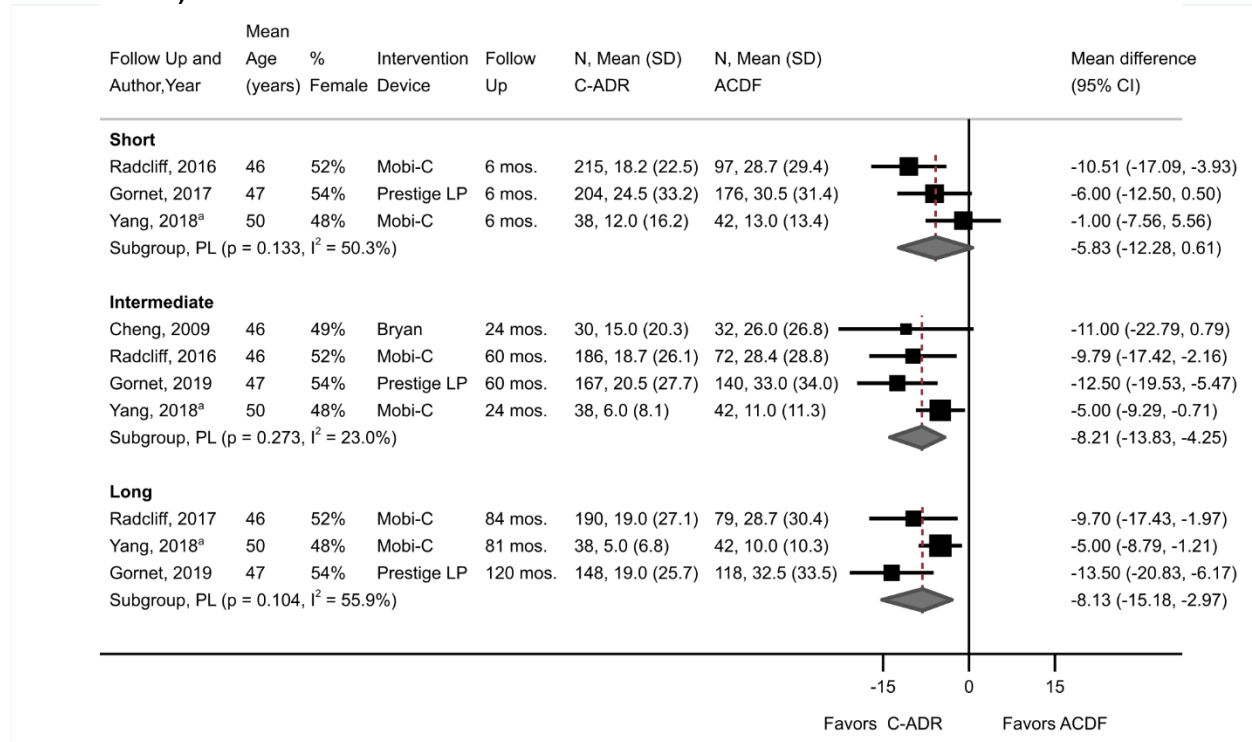
ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA); VAS = visual analogue scale.

There was no difference in VAS neck pain scores (0-100 scale) between cervical arthroplasty and ACDF short term (3 RCTs, N=764, MD -5.83, 95% CI -12.28 to 0.61, $I^2=50.3\%$).^{72,94,99} Cervical arthroplasty was associated with a small pain improvement versus ACDF in the intermediate term (4 RCTs, N=707, MD -8.21, 95% CI -13.83 to -4.25, $I^2=23\%$)^{63,71,94,99} and

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long term (3 RCTs N=615, MD -8.13, 95% CI -15.18 to -2.97, $I^2=55.9\%$)^{71,95,99} (Figure 25). One IDE NRSI that compared a novel cervical arthroplasty versus historical ACDF controls reported no differences in mean VAS neck pain intensity at short- or intermediate term (N=352, 1.8 vs. 2.5 at both times, $p>0.10$).¹⁰⁴

Figure 25. Neck pain scores (0-100): comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SD = standard deviation.
^a Scores estimated from graphs in article.

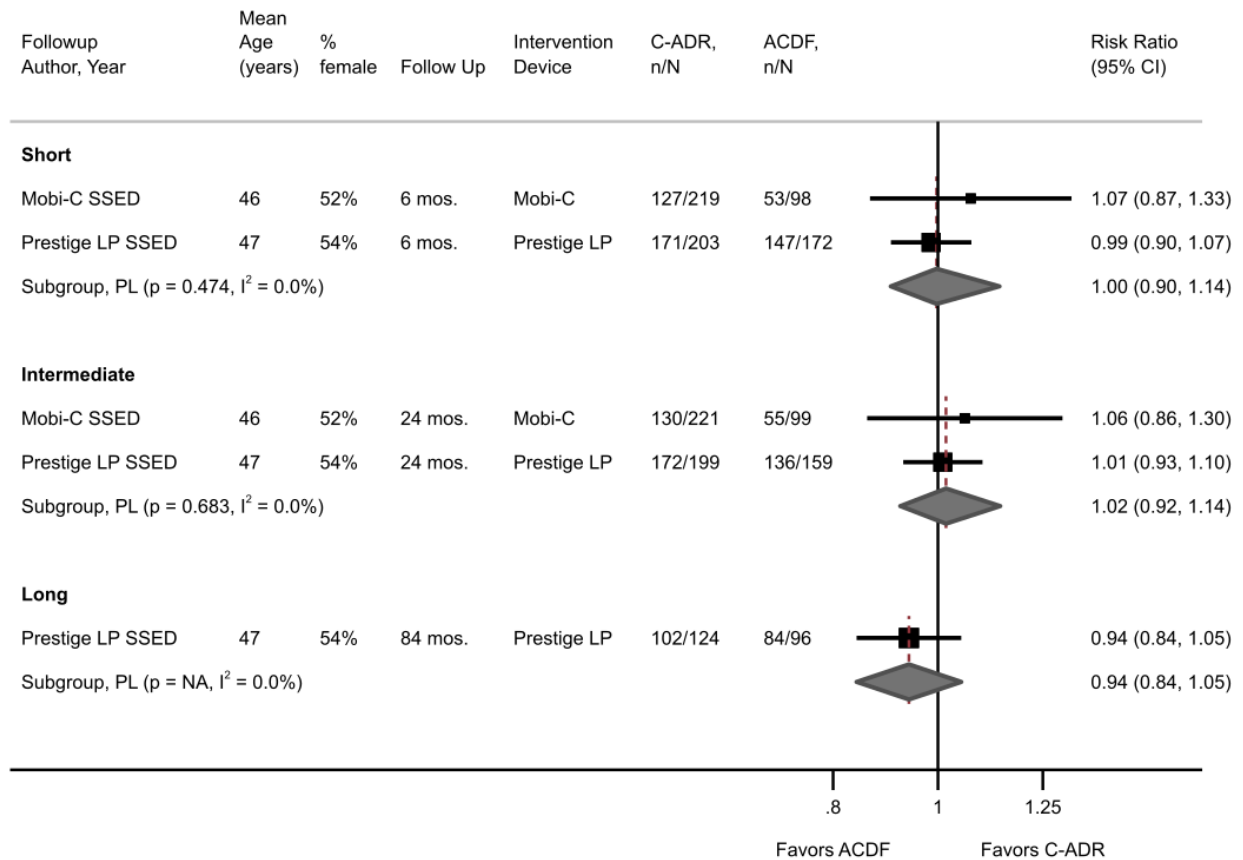
3.9.3.2.2.2 Arm Pain

There was moderate-strength evidence of no difference between cervical arthroplasty and ACDF on arm pain (SOE: Moderate).

Two RCTs (N=727)^{121,122} that compared cervical arthroplasty with ACDF reported arm pain success (response) defined as postoperative ≥ 20 -point improvement on VAS (0-100 scale). Some studies reported arm pain success in both arms. Using conservative estimates (the lower risk ratio), there were no differences in likelihood of arm pain success between cervical arthroplasty and ACDF at short term (2 RCTs, N=692, 70.6% vs. 74.1%, RR 1.0, 95% CI 0.90 to 1.14, $I^2=0\%$),^{121,122} intermediate term (2 RCTs, N=678, 71.9% vs. 74.0%, RR 1.02, 95% CI 0.92 to 1.14, $I^2=0\%$),^{121,122} or long term (1 RCT, N=220, RR 0.94, 95% CI 0.84 to 1.05)¹²² (Figure 26). Estimates and conclusions using the higher risk ratios from the other arm were similar.

3.9 Results, Key Question 8

Figure 26. Arm pain success (≥ 20 -point improvement on VAS): comparison of cervical arthroplasty with ACDF (2-level interventions)

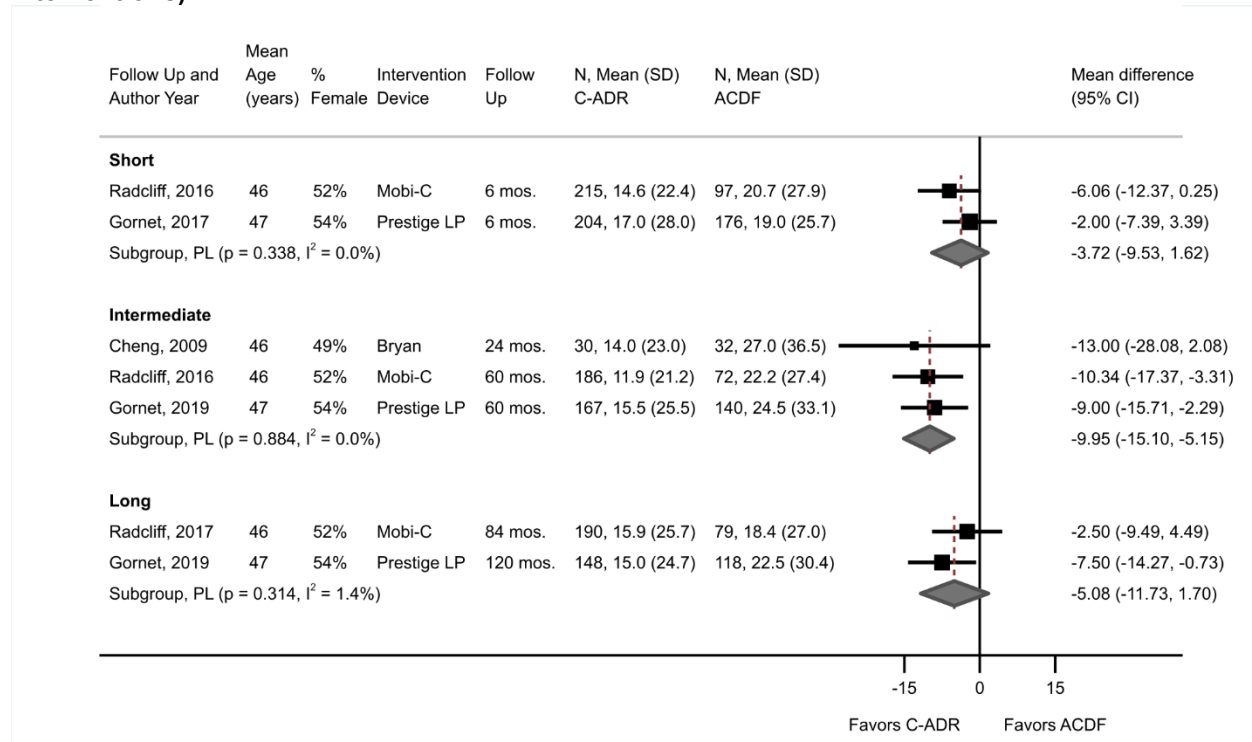


ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA); VAS = visual analogue scale.

Three RCTs (N=792) (in 5 publications)^{63,71,72,94,95} reported arm pain scores (0-100). Some trials reported arm pain scores in both arms. Conservative estimates (using the smaller mean differences) are reported here. There was no difference in VAS arm pain scores (0-100 scale) between cervical arthroplasty and ACDF in the short term (2 RCTs, N=692, MD -3.72, 95% CI -9.53 to 1.62, $I^2=0\%$).^{72,94} Cervical arthroplasty was associated with a small pain improvement versus ACDF at intermediate term (3 RCTs, N=627, MD -9.95, 95% CI -15.10 to -5.15, $I^2=0\%$)^{63,71,94} but not long term (2 RCTs N=535, MD -5.08, 95% CI -11.73 to 1.70, $I^2=1.4\%$)^{71,95} (Figure 27). One IDE NRSI (N=352) that compared a novel cervical arthroplasty versus ACDF using historical controls reported no differences in mean VAS arm pain intensity at short (1.6 vs. 1.7) or intermediate term (1.8 vs. 1.6).¹⁰⁴

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Figure 27. Arm pain scores (0-100): comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SD = standard deviation; SSED = Summary of Safety and Effectiveness Data (FDA).

3.9.3.2.3 Function

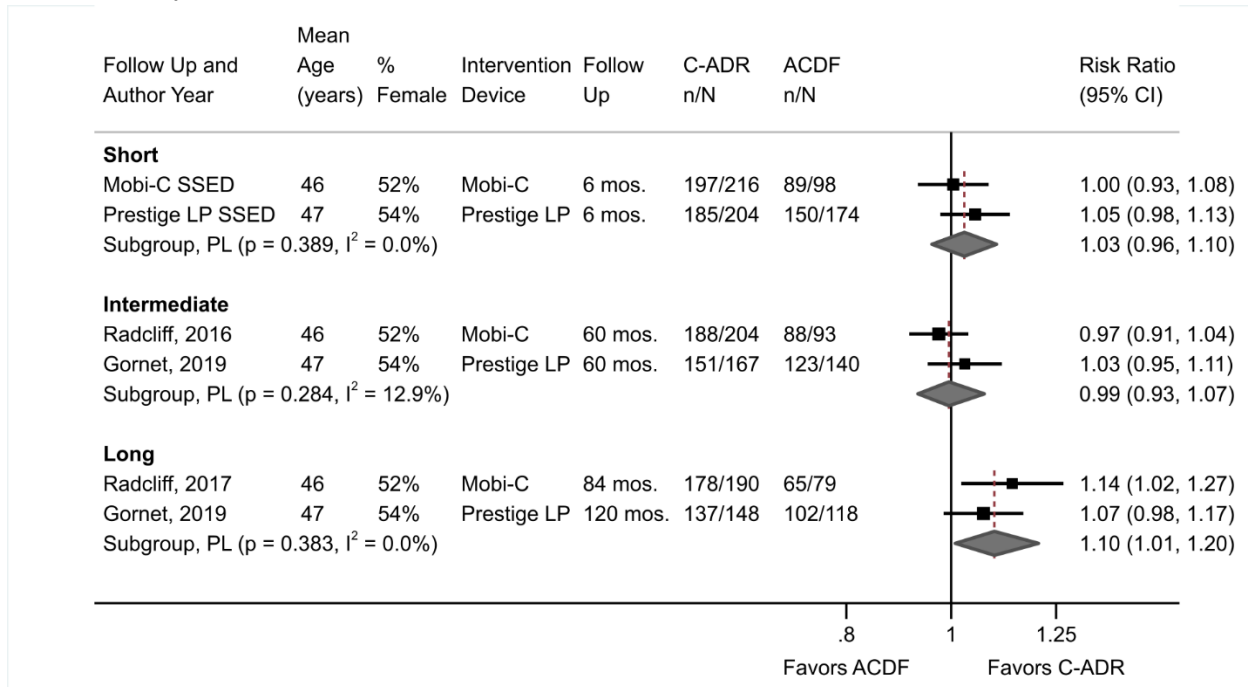
3.9.3.2.3.1 Neurologic Function

There was moderate-strength evidence of no difference between cervical arthroplasty and ACDF on neurologic function (SOE: Moderate).

Two IDE RCTs (N=727) (in 5 publications)^{71,94,95,121,122} that compared cervical arthroplasty with ACDF reported neurologic success (response), defined as maintenance or improvement (compared with preoperative status) in motor function, sensory function, and deep tendon reflexes. In participants with two-level interventions, there was no difference in likelihood of neurologic success between cervical arthroplasty and ACDF at short term (2 RCTs, N=692, 91.0% vs. 87.9%, RR 1.03, 95% CI 0.96 to 1.10, I²= 0%),^{121,122} intermediate term (2 RCTs, N=604, 91.4% vs. 90.6%, RR 0.99, 95% CI 0.93 to 1.07, I²=12.9%)^{71,94} or long term (2 RCTs, N=535, 93.2% vs. 84.8%, RR 1.10, 95% CI 1.01 to 1.20, I²=0%; point estimate below the threshold for a small effect)^{71,95} (Figure 28). The likelihood of neurological success, based on motor, sensory, and myelopathic gait assessments, was similar for cervical arthroplasty and ACDF in one IDE NRSI (N=352, 100% vs. 97.7%).¹⁰⁴

3.9 Results, Key Question 8

Figure 28. Neurologic success: comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA).

Mean JOA scores (0-17 scale) were similar following cervical arthroplasty and ACDF at short term (6 months, 15.2 vs. 14.9, $p > 0.05$), intermediate term (15.4 vs. 15.3, $p > 0.05$), and long term (81 months, 15.4 vs. 15.2, $p > 0.05$) in one RCT (N=96).⁹⁹

3.9.3.2.3.2 General Function

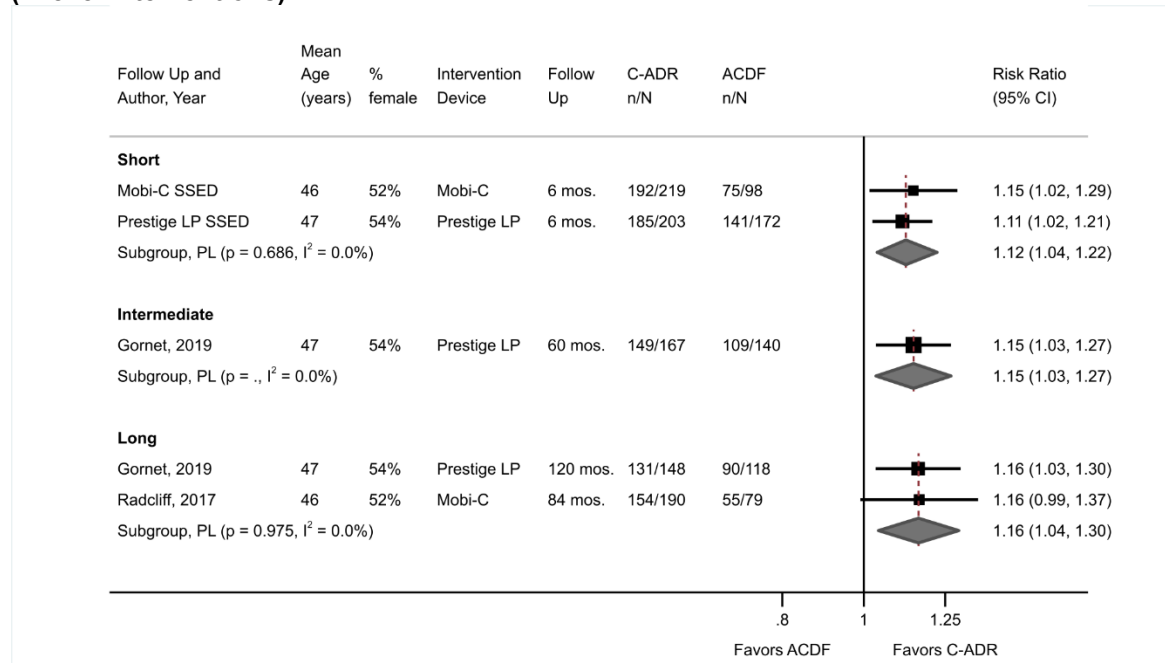
There was moderate-strength evidence of no difference between cervical arthroplasty and ACDF on general function (SOE: Moderate).

3.9.3.2.3.2.1 NDI

Two IDE RCTs (N=727) (in 4 publications)^{71,95,121,122} and one IDE NRSI (N=352)¹⁰⁴ that compared cervical arthroplasty with ACDF reported NDI success defined as postoperative NDI score improvement of ≥ 15 points from baseline. One trial defined NDI success as improvement of ≥ 30 points from baseline and was not included in the meta-analysis.⁶⁶ Based on the threshold of ≥ 15 points from baseline, there were no differences between cervical arthroplasty and ACDF (i.e., although statistically significant, the differences between treatments were below the threshold for a small effect) at short term (2 RCTs, N=692, 89.3% vs. 80.0%, RR 1.12, 95% CI 1.04 to 1.22, $I^2 = 0\%$),^{121,122} intermediate term (1 RCT, N=307, 89.2% vs. 77.9%, RR 1.15, 95% CI 1.03 to 1.27)⁷¹ and long term (2 RCTs, N=535, 84.3% vs. 73.6%, RR 1.16, 95% CI 1.04 to 1.30, $I^2 = 0\%$)^{71,95} (Figure 29). There was no difference in the likelihood of NDI success between cervical arthroplasty and ACDF in one IDE NRSI (N=352, 92.3% vs. 85.5%, $p > 0.05$).¹⁰⁴

3.9 Results, Key Question 8

Figure 29. NDI success (≥ 15 -point improvement): comparison of cervical arthroplasty with ACDF (2-level interventions)



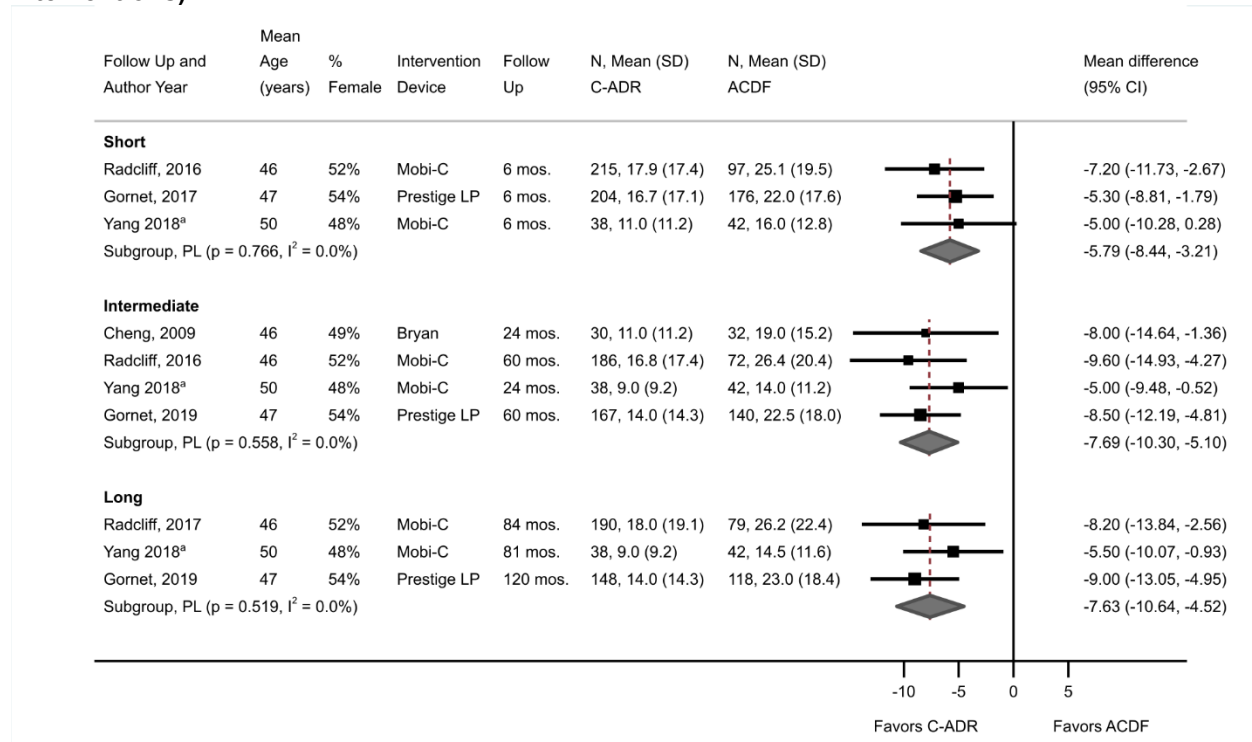
ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; NDI = Neck Disability Index; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA).

One RCT that defined NDI success as improvement of ≥ 30 points from baseline found a moderately higher likelihood of NDI success following cervical arthroplasty versus ACDF at intermediate term (1 RCT, $N=359$, 79.3% vs. 53.4%, RR 1.50, 95% CI 1.21 to 1.86).⁶⁶

Four RCTs ($N=872$) (in 6 publications)^{63,71,72,94,95,99} that compared cervical arthroplasty with ACDF reported NDI scores (0-100, higher score, more limitations). cervical arthroplasty was associated with a small improvement in function based on NDI scores at short (3 RCTs, $N=772$, MD -5.79, 95% CI -8.44 to -3.21, $I^2=0\%$),^{72,94,99} intermediate (4 RCTs, $N=707$, MD -7.69, 95% CI -10.30 to -5.10, $I^2=0\%$),^{63,71,94,99} and long term (3 RCTs, $N=615$, MD -7.63, 95% CI -10.64 to -4.52, $I^2=0\%$)^{71,95,99} (Figure 30).

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Figure 30. NDI scores (0-100): comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; NDI = Neck Disability Index; PL = profile likelihood; SD = standard deviation.

^a Scores estimated from graphs in article.

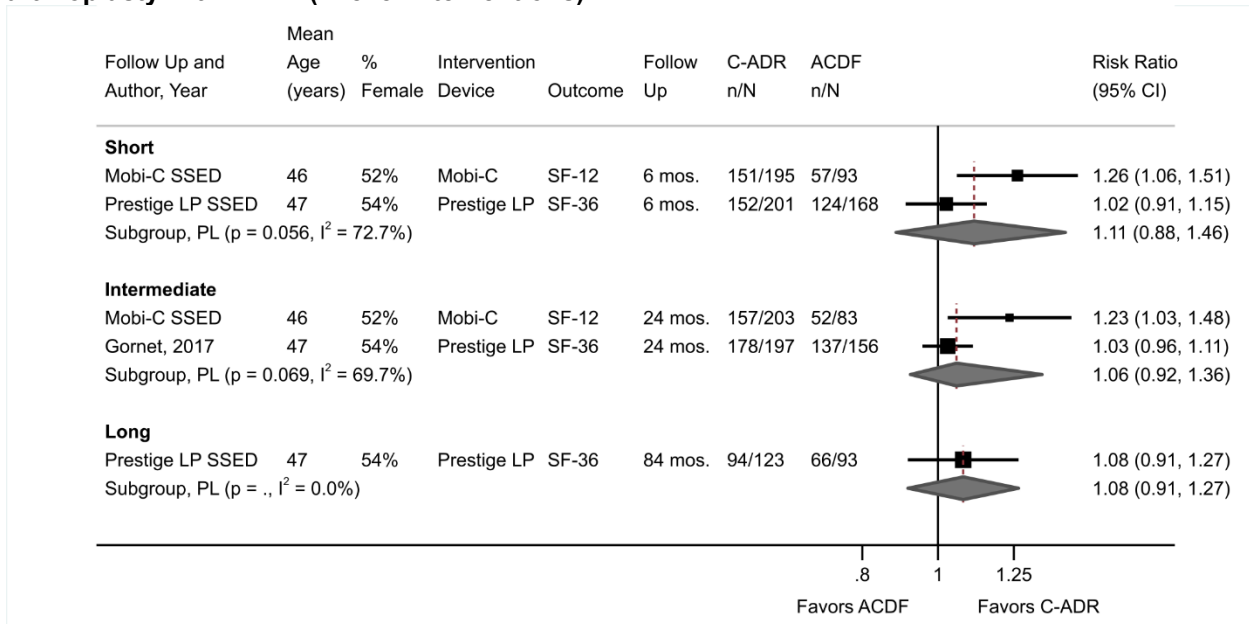
One IDE NRSI (N=352) that compared a novel cervical arthroplasty versus historical ACDF controls found that cervical arthroplasty was associated with a small improvement in function based on the NDI short term (MD 5.7, means 15.1 vs. 20.8, $p < 0.05$); this was not sustained to intermediate term (MD 2.9, means 14.3 vs. 17.2, $p > 0.05$).¹⁰⁴

3.9.3.2.3.2.2 SF-36 PCS and MCS

Two IDE RCTs (N=727) (in 3 publications)^{72,121,122} compared two-level interventions with cervical arthroplasty and ACDF and reported SF-36 PCS and MCS scores (0-100 scale). Success for these component scores was defined as postoperative score improvement of ≥ 15 points from baseline scores. There was no difference between cervical arthroplasty and ACDF in the likelihood of improved function based on PCS success short term (2 RCTs, N=657, 76.5% vs. 69.3%, RR 1.11, 95% CI 0.88 to 1.46, $I^2 = 72.7\%$),^{121,122} intermediate term (2 RCTs, N=639, 83.7% vs. 79.1%, RR 1.06, 95% CI 0.92 to 1.36, $I^2 = 69.7\%$),^{72,121} and long term (1 RCT, N=216, 76.4% vs. 71.0%, RR 1.08, 95% CI 0.91 vs. 1.27)¹²² (Figure 31). Similarly, there were no differences between cervical arthroplasty and ACDF in the likelihood of MCS success at short term (2 RCTs, N=657, 50.3% vs. 45.2%, RR 1.08, 95% CI 0.82 to 1.41, $I^2 = 43.9\%$),^{121,122} intermediate term (2 RCTs, N=639, 62.3% vs. 65.3%, RR 0.98, 95% CI 0.85 to 1.18, $I^2 = 0\%$),^{72,121} and long term (1 RCT, N=216, 53.7% vs. 52.7%, RR 1.02, 95% CI 0.79 to 1.31)¹²² (Figure 32).

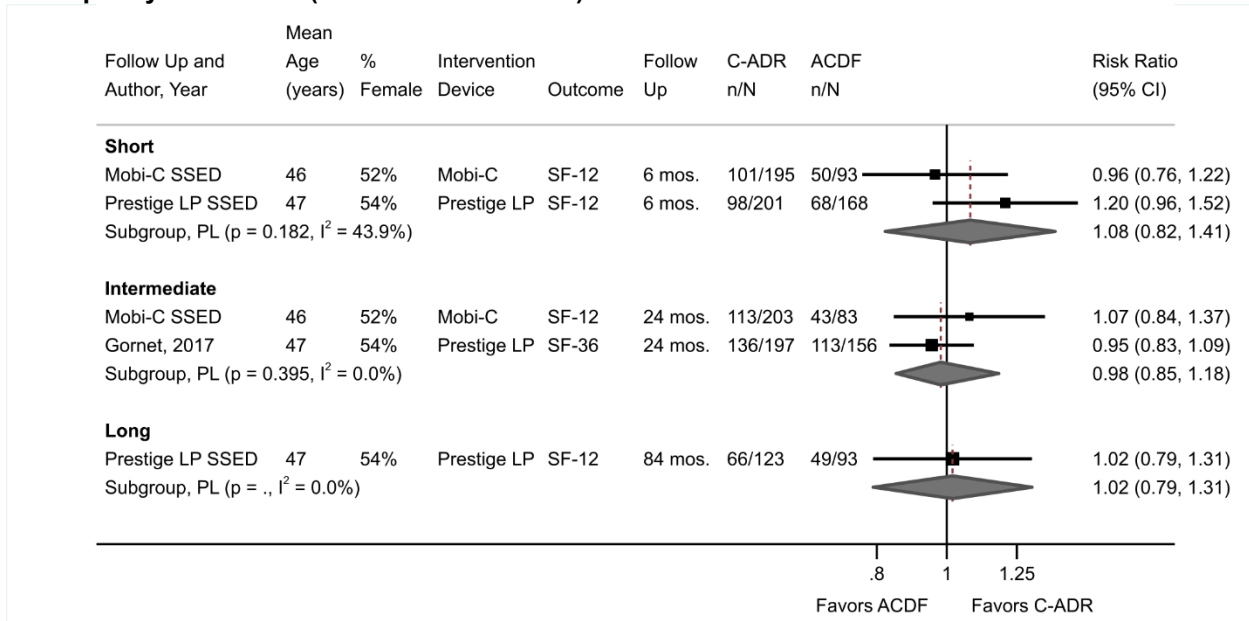
3.9 Results, Key Question 8

Figure 31. SF-36 or SF-12 PCS success (≥15-point improvement): comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PCS = Physical Component Score; PL = profile likelihood; SF-12 = 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey; SSED = Summary of Safety and Effectiveness Data (FDA).

Figure 32. SF-36 or SF-12 MCS success (≥15-point improvement): comparison of cervical arthroplasty with ACDF (2-level interventions)

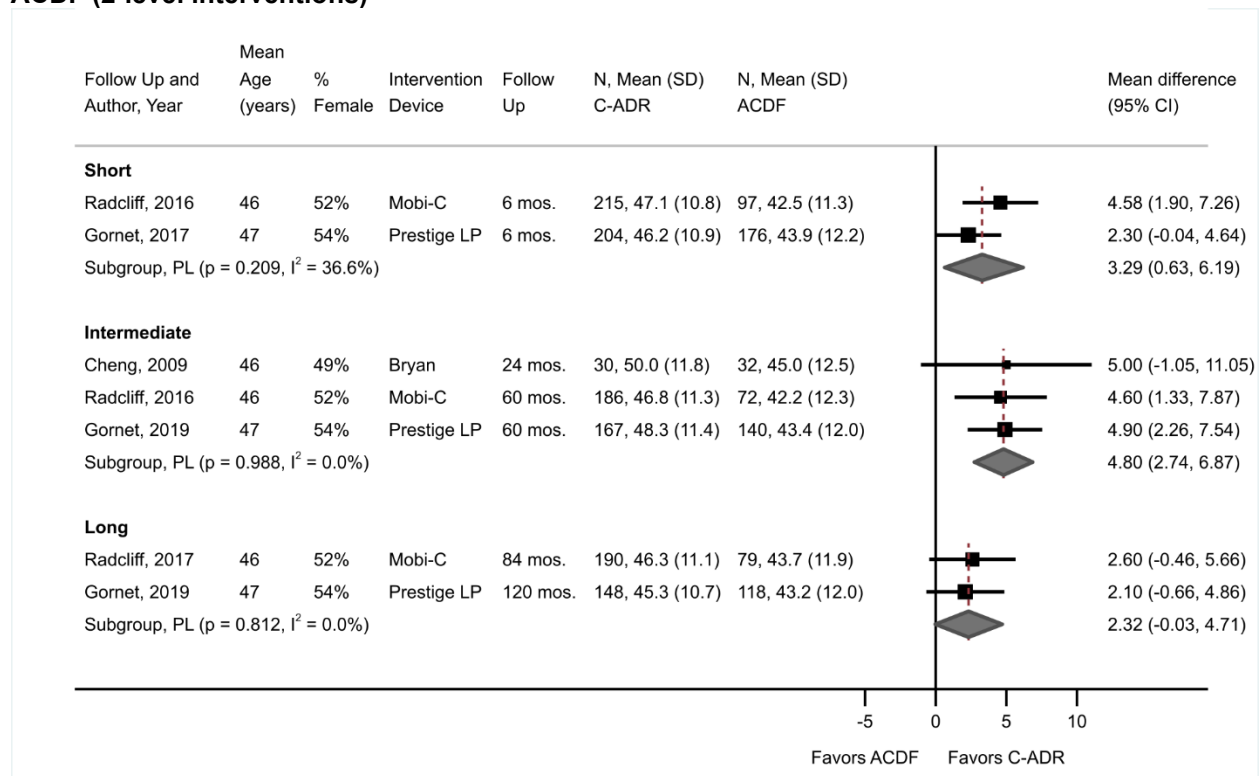


ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; MCS = Mental Component Score; mos. = months; PL = profile likelihood; SF-12 = 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey; SSED = Summary of Safety and Effectiveness Data (FDA).

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Three RCTs (N=792) (in 5 publications)^{63,71,72,94,95} that compared two-level interventions with cervical arthroplasty and ACDF reported SF-36 PCS and MCS scores (0-100 scale). Differences in mean PCS scores did not meet the threshold for a small improvement and were classified as no difference between cervical arthroplasty versus ACDF at short term (2 RCTs, N=692, MD 3.29, 95% CI 0.63 to 6.19, $I^2=36.6\%$),^{72,94} intermediate term (3 RCTs, N=627, MD 4.80, 95% CI 2.74 to 6.87, $I^2=0\%$),^{63,71,94} and long term (2 RCTs, N=535, MD 2.32, 95% CI -0.03 to 4.71, $I^2=0\%$);^{71,95} however, estimates were imprecise (Figure 33). Two RCTs (N=757) reported mean MCS scores which were also not different between groups at short term (1 RCT, N=380, MD 1.00, 95% CI -1.37 to 3.37),⁷² intermediate term (2 RCTs, N=665, MD 1.12, 95% CI -1.07 to 3.29, $I^2=0\%$),^{66,72} or long term (1 RCT, N=269, MD 2.90, 95% CI -0.25 to 6.05)⁹⁵ (Figure 34). One IDE NRSI (N=352) that compared a novel cervical arthroplasty versus matched historical ACDF controls found no difference in mean SF-36 PCS at short (49.2 vs. 46.4, $p<0.05$) or intermediate term (49.2 vs. 47.9).¹⁰⁴

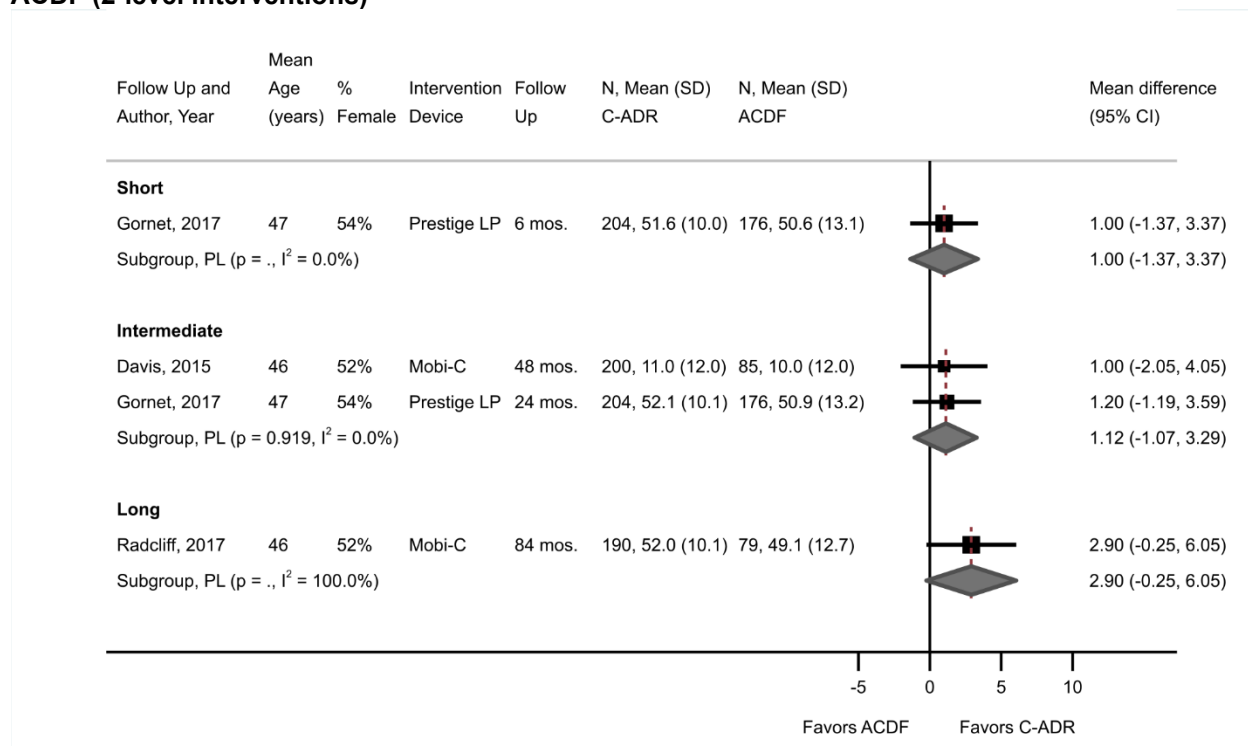
Figure 33. SF-36 or SF-12 PCS scores (0-100 scale): comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; mos. = months; PCS = Physical Component Score; PL = profile likelihood; SD = standard deviation; SF-12= 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey.

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Figure 34. SF-36 or SF-12 MCS scores (0-100 scale): comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; MCS = Mental Component Score; mos. = months; PL = profile likelihood; SD = standard deviation; SF-12= 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey.

3.9.3.2.3.3 Odom’s Criteria

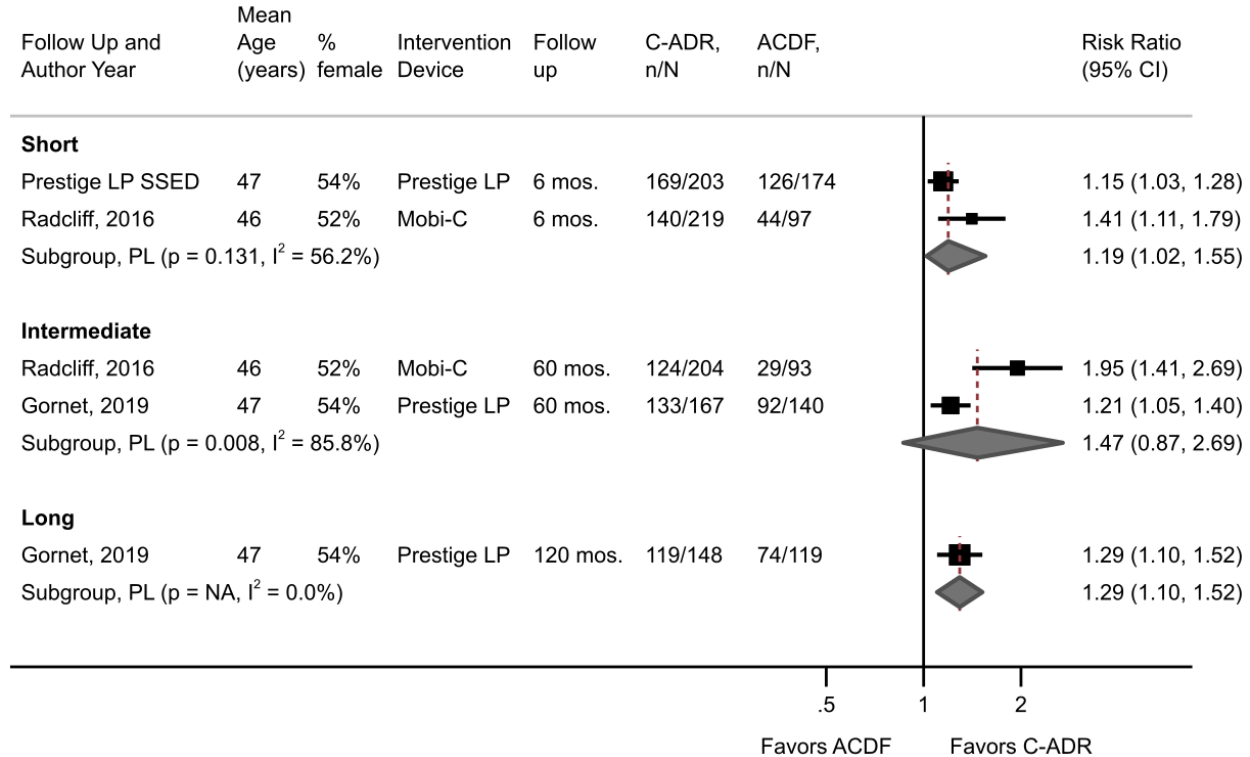
There was no difference between cervical arthroplasty and ACDF for the likelihood of scoring excellent or good on Odom’s criteria at intermediate term in one RCT (N=62, 96.7% vs. 84.4%, RR 1.15, 95% CI 0.97 to 1.34).⁶³

3.9.3.2.4 Overall Success (Composite)

The FDA IDE trials were required to report on overall success, a composite outcome that included a threshold of ≥ 15 -point NDI improvement from baseline, improvement or maintenance of neurologic status, no serious adverse events and no additional surgical procedures that might be considered “failure” (e.g., removal, revision, supplemental fixation). Cervical arthroplasty was associated with a slightly higher likelihood of overall success short term (2 RCTs, N=693, 73.2% vs. 62.7%, RR 1.19, 95% CI 1.02 to 1.56, I²=56.2%)^{94,122} and long term (1 RCT, N=267, 80.4% vs. 62.2%, RR 1.29, 95%CI 1.10 to 1.52).⁷¹ At intermediate term, cervical arthroplasty was also associated with slightly greater likelihood of overall success in two RCTs individually (1 RCT, N=297, 60.1% vs. 31.2%, RR 1.95, 95% CI 1.41 to 2.69 and 1 RCT, N=307, RR 1.21, 95% CI 1.05 to 1.40)^{71,94} (Figure 35).

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Figure 35. Overall success (composite): comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; FDA = Food and Drug Administration; mos. = months; PL = profile likelihood; SSED = Summary of Safety and Effectiveness Data (FDA).

One IDE RCT defined overall success with different NDI success criteria (improvement from baseline of ≥ 30 -points if baseline score was ≥ 60 or $\geq 50\%$ if baseline score was < 60), required adjudication of adverse events and added radiographic success to the criteria listed for the other IDE trials. Cervical arthroplasty was associated with slightly higher likelihood of overall success long-term versus ACDF (1 RCT, $N = 249$, 60.8% vs. 34.6%, RR 1.76, 95% CI 1.27 to 2.44).⁹⁵ One IDE NRSI¹⁰⁴ that compared a novel cervical arthroplasty versus historical ACDF controls defined overall success as ≥ 15 -point NDI improvement, maintenance or improvement in neurological status), no serious adverse event (any implant-associated or implant/surgical procedure-associated) and no additional index-level surgical procedure. Authors reported that overall success was more common in cervical arthroplasty participants versus ACDF ($N = 352$, 86.7% vs. 77.1, $p < 0.05$) based on multiple imputation modeling (numerators not reported; effect estimate could not be calculated).

3.9.3.2.5 Quality of Life

None of the included studies reported quality-of-life measures.

3.9.3.2.6 Reoperation

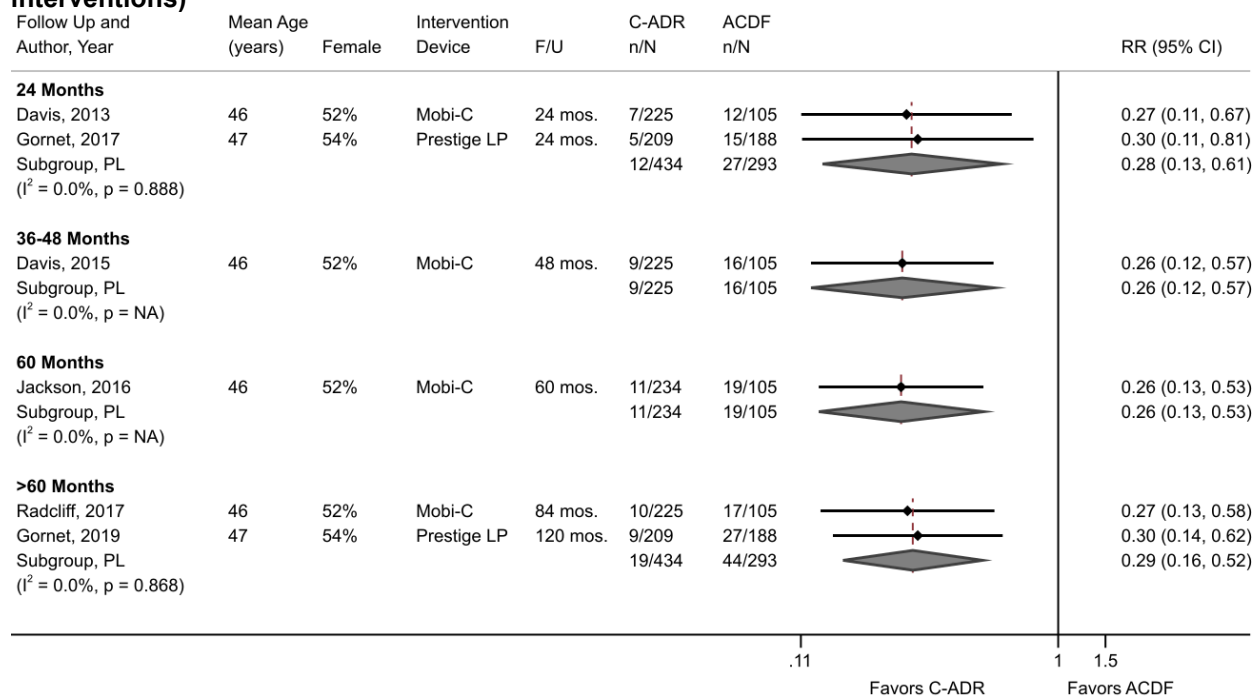
There was low-strength evidence that reoperation is substantially less likely with cervical arthroplasty compared with ACDF at all time points from 24 months and beyond (SOE: Low). Rates of reoperation for ACDF at the index level may be influenced by removal of an existing plate to treat ASD, rather than the indication for reoperation being driven by an issue at the index

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procedure. This may artificially inflate the reported reoperation rate at the index procedure level for ACDF versus cervical arthroplasty. The clinical relevance of removing the plate as a part of a procedure addressing ASD is minimal.

Reoperation included any additional procedure that involved the index level and was substantially less likely with cervical arthroplasty at all times reported across IDE trials, however estimates were imprecise. Effect estimates were consistent across reported times: up to 24 months (2 RCTs, N=727, 2.8% vs. 9.2%, RR 0.28, 95% CI 0.13 to 0.61, $I^2=0\%$),^{65,72} 36 to 48 months (1 RCT, N=330, 4.0% vs. 15.2%, RR 0.26, 95% CI 0.12 to 0.57),⁶⁶ 60 months (1 RCT, N=330, 4.7% vs. 18.1%, RR 0.26, 95% CI 0.13 to 0.53),⁸⁰ and >60 months (2 RCTs, N=727, 4.4% vs. 15.0%, RR 0.29, 95% CI 0.16 to 0.52, $I^2=0\%$)^{71,95} (Figure 36). One IDE NRSI that compared a novel cervical arthroplasty versus historical ACDF controls also reported that secondary surgical interventions were less common with cervical arthroplasty (N=352, 2.2% vs. 8.8%).¹⁰⁴

Figure 36. Reoperation at the index level: comparison of cervical arthroplasty with ACDF (2-level interventions)

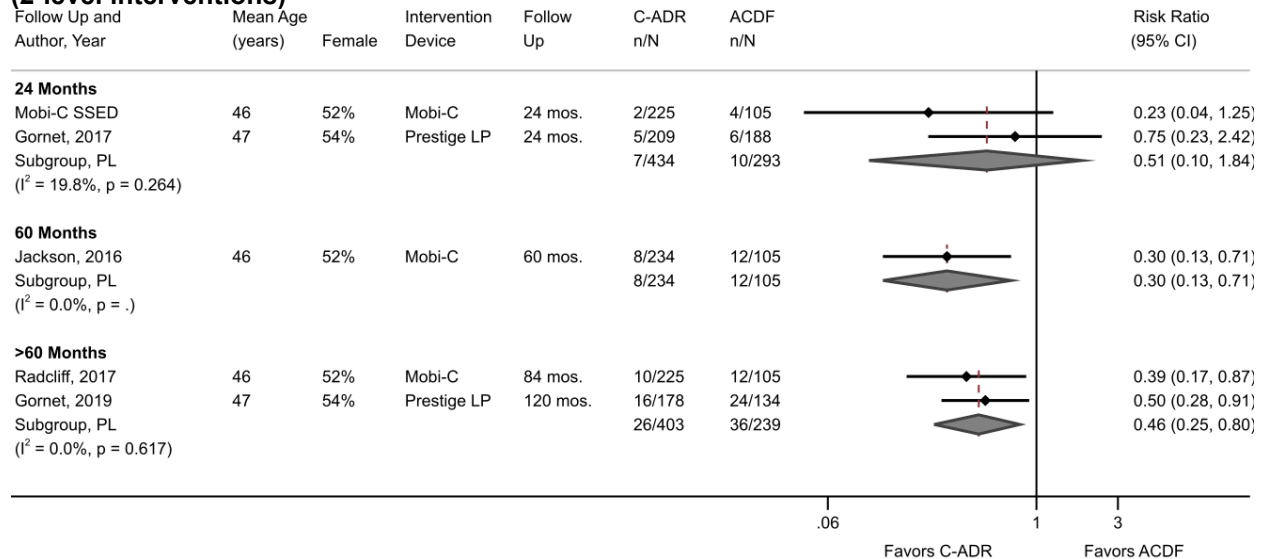


ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; mos. = months; PL = profile likelihood.

Subsequent surgery rates at adjacent levels were similar between cervical arthroplasty and ACDF at 24 months (2 RCTs, N= 727, 1.6% vs. 3.4%, RR 0.51, 95% CI 0.10 to 1.84, $I^2=19.8\%$),^{72,121} but substantially less common with cervical arthroplasty versus ACDF at 60 months (1 RCT, N=339, 3.4% vs. 11.4%, RR 0.30, 95% CI 0.13 to 0.71)⁸⁰ and >60 months (2 RCTs, N=642, 6.5% vs. 15.1%, RR 0.46, 95% CI 0.25 to 0.80, $I^2= 0\%$).^{71,95} Across trials, indications for operation at adjacent levels were not consistently described (Figure 37).

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Figure 37. Subsequent surgery at adjacent level: comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; mos. = months; PL = profile likelihood.

3.9.3.2.7 Harms

Cervical arthroplasty was associated with a slightly lower likelihood of experiencing any adverse event at 24 months based on low-strength evidence (SOE: Low), but there was no difference between procedures at 120 months for WHO Grade 3 or 4 adverse events (SOE: Low). There was insufficient evidence for neurological deficits or events and for mortality (SOE: Insufficient).

All IDE RCTs and one IDE NRSI provided information on adverse events and harms.

3.9.3.2.7.1 Neurologic Deficit

Two RCTs (N=395) in 3 publications^{63,66,95} reported neurologic events using varied terminology. One RCT (N=65)⁶³ reported that no neurologic complications occurred with cervical arthroplasty or ACDF through 24 months. There was no difference between neurologic deterioration at 48 months (6.2% vs. 7.6%, RR 0.82, 95% CI 0.35 to 1.89) in one IDE trial⁶⁶ but a subsequent publication of the trial reported substantially lower incidence of neurological failure, defined as a decrease in sensory, reflex or motor function from preoperative status, with cervical arthroplasty versus ACDF (6.4% vs. 17.1%, RR 0.36, 95% CI 0.19 to 0.70) at 84 months.⁹⁵

3.9.3.2.7.2 Mortality

Cumulative mortality was similar between two-level cervical arthroplasty (2 deaths) and ACDF (3 deaths) through 120 months in one IDE trial, but authors did not provide cause of death (N=397, 1.0% vs. 1.6%; RR 0.60, 95% CI 0.10 to 3.55);⁷¹ there was one death in both groups by 12 months (0.5% vs. 0.5%)⁷² and two deaths in both groups by 84 months (1.0% vs. 1.1%).⁸³

3.9.3.2.7.3 Serious Adverse Events

Serious adverse events were reported for two IDE trials (N=727) of different devices (five publications)^{65,66,71,72,83} but were defined differently across reports. One trial's initial report found events were common and that fewer cervical arthroplasty (Mobi-C) participants experienced one

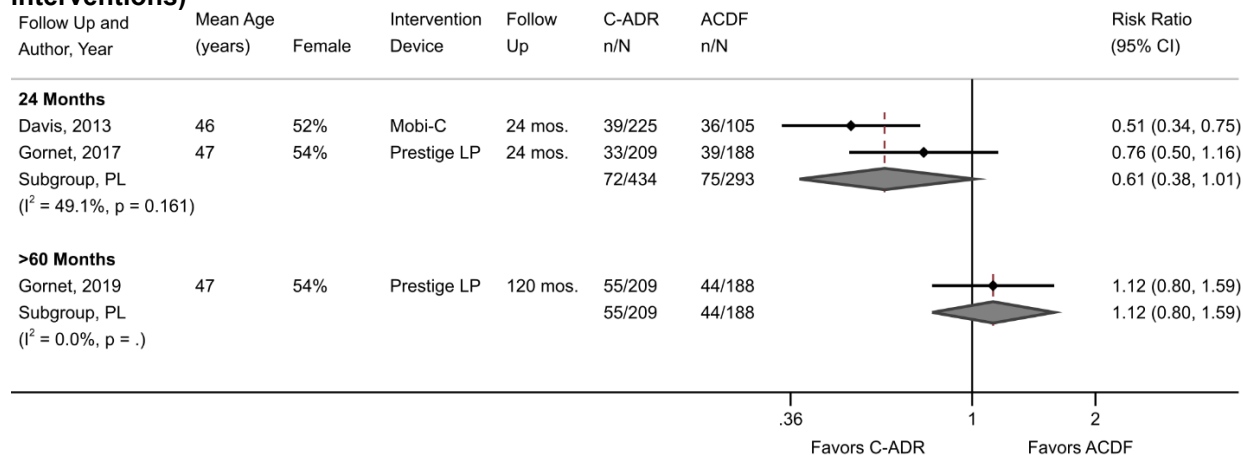
3.9 Results, Key Question 8

or more serious adverse events (23.9% vs. 32.4%)⁶⁵ up to 24 months but included events unrelated to the device, surgery, or cervical spine as well as those that may not have required additional medical intervention. In a subsequent report of this trial, following adjudication of events by a clinical events committee, fewer events were considered serious and they continued to be less common with cervical arthroplasty versus ACDF, but effect estimates were imprecise (1 RCT, N=330, 4.0% vs. 7.6%, RR 0.75, 95% CI 0.53 to 1.08) at 24 months.⁶⁶ The IDE trial of another device (Prestige-LP), also included a broad range of events and reported fewer Grade 3 or 4 adverse events with cervical arthroplasty at 24 months versus ACDF (1 RCT, N=397, 34.4% vs. 47.9%).⁷² Cervical arthroplasty was associated with slightly lower likelihood of serious adverse events across the two trials at 24 months (2 RCTs, N=727, 29.3% vs. 42.3%, RR 0.73, 95% CI 0.58 to 0.93, I²=0%)^{65,72} using the broad definition of events. There was no difference between groups in the frequency of WHO Grade 3 or 4 adverse events at 120 months in one IDE trial (N=397, 66.7% vs. 70.9%, RR 0.93, 95% CI 0.80 to 1.09).⁷¹

3.9.3.2.7.4 Device-Related Adverse Events

Device-related adverse event definitions, types of events and adjudication varied across RCTs. One trial included a range of events such as anatomy/technical difficulty, trauma as well as neurological events while others did not provide specifics. Some device-related events may only occur with cervical arthroplasty, others may only occur with ACDF (e.g., nonunion). Some events may not be persistent or serious (e.g., dysphagia or dysphonia). Two-level cervical arthroplasty was associated with a moderately lower likelihood of device-related events at 24 months compared with ACDF (2 RCTs, N=727, 16.6% vs. 25.6%, RR 0.61, 95% CI 0.38 to 1.01, I²=49.1%)^{65,72} but there was no difference between groups at 120 months in one of these trials (N=397, 26.3% vs. 23.4%, RR 1.12, 95% CI 0.80 to 1.59)⁷¹ (Figure 38). When only serious device-related adverse events were considered, as adjudicated by committee or as WHO grade 3 or 4 events, cervical arthroplasty was associated with a substantially lower likelihood of such serious events compared with ACDF at 24 months in one trial (N=397, 1.9% vs. 5.9%, RR 0.33, 95% CI 0.11 to 1.01)⁷² but there was no difference between groups at 120 months in this same trial (RR 0.48, 3.8% vs. 8.1%, 95% CI 0.21 to 1.11)⁷¹ or at 60 months in a second trial (N=330, 4.4% vs. 8.6%, RR 0.52, 95% CI 0.22 to 1.24),⁹⁴ however, the estimates were very imprecise.

Figure 38. Device-related adverse events: comparison of cervical arthroplasty with ACDF (2-level interventions)



ACDF = anterior cervical discectomy and fusion; C-ADR = cervical artificial disc replacement (cervical arthroplasty); CI = confidence interval; F/U = followup; mos. = months; PL = profile likelihood.

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Device-related adverse events were similar for cervical arthroplasty and ACDF in one IDE NRSI (3.8% vs. 3.5%).¹⁰⁴

3.9.3.2.7.5 Dysphagia

Dysphagia was reported by several RCT publications (N=475), but the severity was unclear in most cases.^{63,94,99} Dysphagia rate ranges were broad for cervical arthroplasty (0% to 24%) and for ACDF (0% to 38%) across these publications. One IDE trial (N=397) reported low rates of Grade 3 or 4 dysphagia that differed slightly across two post-FDA approval study publications, possibly reflecting different analytic methods. Rates did not differ by procedure at 84 months (1.3% vs. 0%)⁸³ or 120 months (0.6% vs. 0.7%).⁷¹

3.9.3.2.7.6 Heterotopic Ossification

Grade 3 or 4 HO, considered clinically relevant HO, may be of concern with cervical arthroplasty. Across two IDE RCTs evaluating 2-level interventions (N=337, cervical arthroplasty arms), 35.4 percent of participants developed Grade 3 or 4 HO (29.7% at 60 months in 1 RCT and 42.4% at 84 months in 1 RCT).^{83,94} One of these trials (N=186, cervical arthroplasty arm)⁹⁴ reported Grade 4 HO separately which occurred in 9.7 percent of cervical arthroplasty participants by 60 months.⁹⁴ The FDA IDE NRSI (N=182, cervical arthroplasty arm) also reported HO; at the superior index level, grade 3 and 4 HO occurred in 8 participants (5%) each and at the inferior index level, in 17 (10%) and five (3%) participants, respectively, at 24 months.¹⁰⁴ The frequency of Grade 1 or 2 HO was not consistently reported and ranged from 0 to 28.9 percent across three trials (N=278, cervical arthroplasty arms, range 31 to 209) evaluating 2-level interventions.^{63,72,99}

3.9.3.2.8 Differential Effectiveness (HTE)

One IDE trial that compared 2-level cervical arthroplasty and ACDF provided subgroup analysis on the presence of radiculopathy alone (N=287) and myelopathy alone or myelopathy with radiculopathy (N=110) for pain, function, and adverse events at 24 and 84 months but did not formally test for interaction.⁷³ Visual inspection of effect estimates and overlap in estimate variability and subgroup estimates suggest no differential effectiveness or harms, although the study may have been underpowered to evaluate this.

3.9.3.3 Mixed 1-, 2-, or 3-Level Cervical Arthroplasty Versus ACDF

Three RCTs compared 1- 2- or 3-level cervical arthroplasty and ACDF (i.e., mixed levels).^{62,64,74} Sample sizes ranged from 53 to 83 (total N=196). Across two trials,^{62,64} 54 to 83 percent of participants had single-level procedures, 17 to 37 percent had 2-level procedures, and in one of these trials⁶² 8 percent had 3-level procedures; one trial used the Bryan[®] disc and the other used the Prestige-II[®] disc, which are both FDA-approved for single-level indications only. The third trial enrolled participants who underwent 1- or 2-level procedures but did not provide the proportions for each.⁷⁴ The RCTs were conducted in China, India and Spain. Four additional NRSIs compared harms for mixed-level cervical arthroplasty and ACDF.^{107,110-112}

3.9.3.3.1 Fusion

One RCT (N=42) reported intermediate-term fusion success in 90.5 percent of participants in the ACDF arm.⁶² This RCT also reported fusion in the cervical arthroplasty arm, but this can be attributed to participant crossover after initial randomization.

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3.9.3.3.2 Pain

There was low-strength evidence of no difference between treatment with cervical arthroplasty and ACDF on neck pain (SOE: Low).

There was no difference in median VAS (0 to 10) neck pain scores at 60 months between cervical arthroplasty (3.6, interquartile range [IQR] 3.2 to 4.1) and ACDF (median 3.9, IQR 3.0 to 4.4) at 60 months ($p=0.203$) in one trial ($N=50$).⁷⁴ No other pain measures were reported.

3.9.3.3.3 Function

3.9.3.3.3.1 Neurologic Function

There was inadequate evidence to determine the effect of cervical arthroplasty versus ACDF on neurologic function (SOE: Insufficient).

Participants who received cervical arthroplasty had higher mean JOA scores (0-17) at 36 months compared with ACDF in one RCT ($N=81$; 15.4 vs. 14.7 [estimated from graphs in article]; $p=0.016$).⁶²

3.9.3.3.3.2 General Function

There was inadequate evidence to determine the effect of cervical arthroplasty versus ACDF on general function (SOE: Insufficient).

One RCT ($N=81$) reported three different measures of general function at 36 months.⁶² Participants who received cervical arthroplasty had better (i.e., lower) mean NDI scores (12 vs. 18 [estimated from graphs], on a 0 to 50 scale, $p<0.001$) and better (i.e., higher) mean SF-36 PCS scores (50.5 vs. 44.5 [estimated from graphs], on a 0 to 100 scale, $p<0.05$) compared with ACDF, but there were no differences between treatments in the proportion of participants who achieved an excellent (58.5% vs. 58.5%, RR 1.02, 95% CI 0.70 to 1.47) or good (34.1% vs. 25%, RR 1.37, 95% CI 0.69 to 2.71) result according to Odom's criteria. A second RCT ($N=50$) reported no difference between groups in NDI scores (median 7, IQR 6 to 8, for both groups) at 60 months.⁷⁴

3.9.3.3.4 Quality of Life

None of the included studies reported on quality-of-life measures.

3.9.3.3.5 Harms

There was inadequate evidence to determine the effect of cervical arthroplasty and ACDF on harms or adverse events (SOE: Inadequate).

Two RCTs^{62,64} and four NRSIs^{107,110-112} reported harms and adverse events.

3.9.3.3.5.1 Neurological Complications

One RCT ($N=53$) reported one case of transient recurrent nerve paralysis in both groups (cervical arthroplasty 4% vs. ACDF 3.6%, RR 1.12, 95% CI 0.07 to 16.98) that resolved within 3-4 weeks and one case of postoperative worsening of arm pain and neurological deficit in the ACDF group (3.6%).⁶⁴ A second trial ($N=83$) reported that no intraoperative neurologic complications occurred in either group.⁶² One large NRSI based on administrative data reported no difference between cervical arthroplasty and ACDF in the frequency of neurological complications (cervical arthroplasty 1.6% vs. ACDF 1.7%, adjusted OR 1.18, 95% CI 0.38 to 3.72), however specific types or timing of neurological events were not reported.¹⁰⁷ Another large NRSI ($N=1,014$) that conducted a propensity score matched analysis reported no

3.9 Results, Key Question 8

differences between treatment arms in the frequency of limb paralysis through 30 days (2.4% vs. 2.4%) and 12 months (8.9% vs. 7.5%); no other details were provided.¹¹¹ This same study reported spinal complications (0% vs. 0.4% at 30 days; 0% vs. 1.0% at 12 months), neurological complications (0% at 30 days; 0.4% vs. 0.2% at 12 months), and nerve root complications (none at any time), but again no specifics were given.

3.9.3.3.5.2 Mortality

One RCT (N=83) reported that no deaths occurred in either group through 90 months.⁶² Mortality was rare for both cervical arthroplasty and ACDF across two large NRSIs based on administrative data and there was no difference between procedures: 0.5 and 2.2 percent, respectively, (OR 0.56, 95% CI 0.08 to 4.11) in one NRSI (N=143,060)¹⁰⁷ and 0.6 versus 0 percent through 12 months postoperative in the other (N=1,014 after matching).¹¹¹

3.9.3.3.5.3 Serious Adverse Events

One RCT (N=83) reported one case of DVT (2.4%) in the cervical arthroplasty group.⁶² There were no differences between cervical arthroplasty and ACDF in the frequency of pulmonary embolism (0.5% vs. 0.8%, OR 1.43, 95% CI 0.19 to 10.7) or DVT (2.2% vs. 2.4%, OR 1.07, 95% CI 0.33 to 3.40) in one large NRSI (N=143,060).¹⁰⁷ Similarly, there were no differences between cervical arthroplasty and ACDF in the risk of thromboembolic events across two large NRSIs that performed propensity-score matching (N=1,014 and 1,368): pulmonary embolism at 30 days postoperative (0% vs. 0.2%-0.3%, respectively) in both studies^{111,112} and through 12 months in one study (1.0% vs. 0.8%)¹¹¹ and DVT at 30 days postoperative in one study (0% vs. 0.3%).¹¹²

One RCT (N=83) reported that no cerebrospinal fluid leakage occurred.⁶² Cerebrospinal fluid leak was rare for both cervical arthroplasty (0.5%) and ACDF (0.2%) and there was no difference between procedures (OR 2.19, 95% CI 0.29 to 16.3) in one large NRSI based on administrative data.¹⁰⁷

In one RCT (N=53), one participant (3.6%) who underwent 2-level ACDF developed a wound hematoma that needed urgent evacuation;⁶⁴ another RCT reported that there were no cases of wound hematoma.⁶² One of these trials reported that three ACDF participants (10.7%, N=28) had recurrent cervical pain between 3 and 6 months which required local infiltration (not further explained).⁶⁴ There were no cases of wound dehiscence at 30 days in one NRSI (N=1,368 after matching)¹¹² and similar frequencies of wound complications for cervical arthroplasty and ACDF through 12 months in a second NRSI (N=1,014 after matching),¹¹¹ but the severity was unclear.

One case (2.4%, N=41) of heterotopic ossification (i.e., spontaneous fusion/bridging bone) was reported in the cervical arthroplasty group in another RCT.⁶²

Although dysphagia was reported in one RCT⁶² and two NRSIs,^{107,111} the severity of dysphagia was unclear. A number of other serious or potentially serious adverse events were reported across the two large NRSIs that conducted propensity score matched analyses (N=2,382). These events were rare and occurred with similar frequency in the cervical arthroplasty and ACDF groups, respectively, through 30 days: cerebrovascular accident (0% vs. 0%-0.6%), sepsis or septic shock (0% vs. 0% to 0.2%), myocardial infarction (0% to 0.1%, both groups), mechanical ventilation (0%; 1 NRSI),¹¹² unplanned intubation (0.3% vs. 0%; 1 NRSI),¹¹² deep infection (0%; 1 NRSI),¹¹² cellulitis (0% vs. 0.2%; 1 NRSI)¹¹¹ and dural tear (0.2% vs. 0%; 1 NRSI).¹¹¹ One of these trials reported events through 12 months with more cerebrovascular accidents reported in the ACDF group (0% vs. 2.4%, p<0.001); there were no

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differences between groups for all other adverse events longer term (dural tear, 0.6% vs. 0%; myocardial infarction, 0.4% vs. 0.6%; sepsis, 0.6% vs. 1.0%; cellulitis, 2.0% vs. 2.2%),

3.9.3.3.6 Reoperation and Subsequent Surgery

One RCT (N=53) reported reoperation at the index level in one (4%) cervical arthroplasty and two (7.1%) ACDF participants between 12 and 36 months (RR 0.56, 95% CI 0.05 to 5.81).⁶⁴ A second trial (N=83) reported that no participants in either group required reoperation at the index level through 36 months.⁶² One NRSI did not provide adjusted effect estimates but reported the proportions of cervical arthroplasty and ACDF patients who required reoperation at the index level at 12 months (1.7% vs. 2.4%) and 24 months (0% vs. 3.6%) and subsequent surgery at adjacent levels at 12 months (1.7% vs. 2.4%) and 24 months (3.3% vs. 5.1%).¹¹⁰ Across the two NRSIs that did attempt to control for confounding (propensity score adjusted analyses), over the first 30 postoperative days, 0.4 percent of cervical arthroplasty versus 1.0 percent of ACDF underwent any reoperation (not further specified) in one study (N=1,368)¹¹² and in the second study, 2.8 versus 1.0 percent had a revision surgery, 0.4 versus 0.2 percent had a drainage/evacuation, and no patient had a hardware removal in the other study (N=1,014).¹¹¹ At 12 months in the latter study, the proportion of patients requiring revision surgery rose to 10.7 versus 7.1 percent; the need for drainage/evacuation (0.8% for both) and hardware removal (0.2% for both) remained low.

3.9.3.3.7 Differential Effectiveness (HTE)

None of the included trials that compared 1-, 2-, or 3 level cervical arthroplasty and ACDF interventions reported differential effectiveness based on patient or other characteristics.

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3.10 Key Question 9: In patients undergoing anterior cervical discectomy and fusion, what are the comparative effectiveness and harms of surgery based on interbody graft material or device type?

3.10.1 Standalone Cage Versus Plate and Cage

3.10.1.1 Key Findings

- There was moderate-strength evidence of no difference in fusion rates between standalone cages versus plate and cage (SOE: Moderate).
- There was low-strength evidence of no differences between standalone cages versus plate and cage on arm pain, function, and quality of life (SOE: Low); there was inadequate evidence for neck pain (SOE: Insufficient).
- There was low-strength evidence of no difference between standalone cage versus plate and cage on adjacent-level ossification (SOE: Low); evidence was inadequate for subsidence (sinking of vertebral endplates around the graft) and other adverse events (SOE: Insufficient).

3.10.1.2 Description of Included Studies

Nine RCTs (N=619)¹²⁴⁻¹³² compared a standalone device with a traditional plate and cage (Appendix C). The average mean followup duration was 21 months (range immediately postoperative to 36 months). Six trials were conducted in China, two in the United States, and one each in Germany and Japan.

The average study mean age of participants was 52 years (range 41 years to 63 years); the average proportion of females was 42 percent (range 9% to 54%). Few trials reported exact proportions of patients with radiculopathy, myelopathy, or myeloradiculopathy. One trial enrolled only participants with radiculopathy without myelopathy¹³⁰ and two trials enrolled only participants with myelopathy but did not report the proportion of participants with radiculopathy.^{127,129} Most trials enrolled participants with 1-level disease,^{126,128,130} 1- to 2-level disease,^{131,132} or 2-level disease.¹²⁵ One trial each treated participants with 1- to 3-level disease,¹²⁴ 3-level disease,¹²⁷ and 2- to 4-level disease.¹²⁹

All studies were rated moderate risk of bias with the exception of one trial that was rated high risk of bias (Appendix D).¹²⁶ Methodological limitations included unclear randomization techniques, unclear blinding, and unclear attrition. Evidence for neck pain in standalone devices versus traditional plate and cage was rated insufficient due to conflicting findings. Evidence for harms other than adjacent-level ossification was rated insufficient due to the infrequency of adverse events (Appendix G).

3.10.1.3 Detailed Analysis

3.10.1.3.1 Fusion

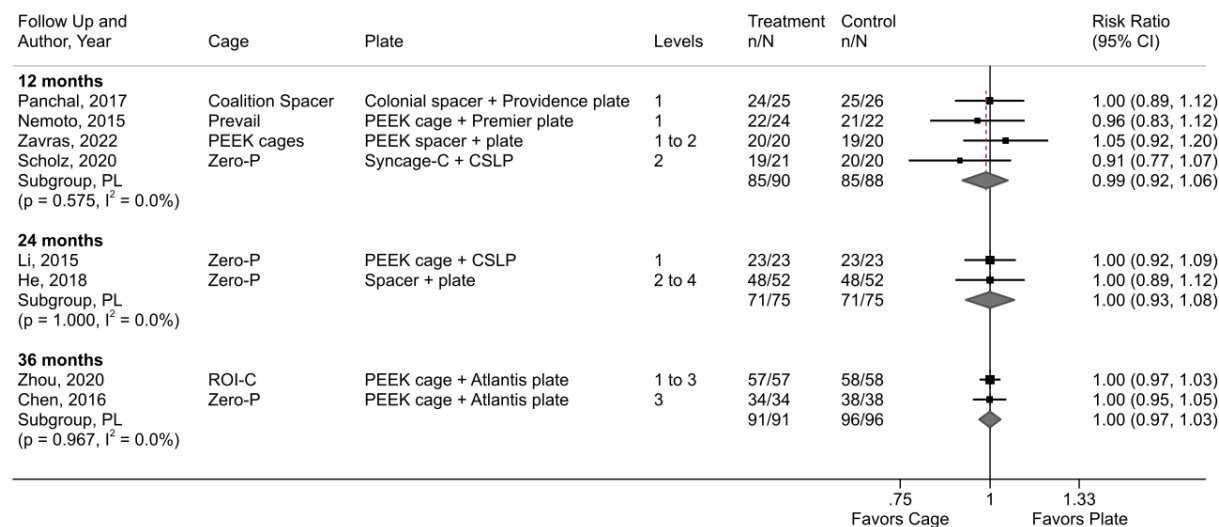
There was moderate-strength evidence of no difference in fusion rates between standalone cages versus plate and cage in participants undergoing ACDF (SOE: Moderate).

Almost all participants who underwent ACDF with either a standalone cage or with a traditional plate and cage (N=515) experienced fusion at 12 months (4 RCTs, N=178, 94% vs. 97%, RR 0.99, 95% CI 0.92 to 1.06, I²=0%), 24 months (2 RCTs, N=150, 95% vs. 95%, RR

3.10 Results, Key Question 9

1.00, 95% CI 0.93 to 1.08, $I^2=0\%$) and 36 months (2 RCTs, N=187, 100% vs. 100%, RR 1.00, 95% CI 0.97 to 1.03, $I^2=0\%$) (Figure 39). This was true when fusion was limited to one level or involved multilevel fusion. One trial did not report fusion as an outcome.¹³¹ (SOE: Moderate)

Figure 39. Fusion, standalone cage versus traditional plate and cage



CSLP = cervical spine locking plate; CI = confidence interval; PEEK = polyetheretherketone; PL = profile likelihood; ROI-C = ROI-C implant system; Zero-P = zero-profile

3.10.1.3.2 Pain

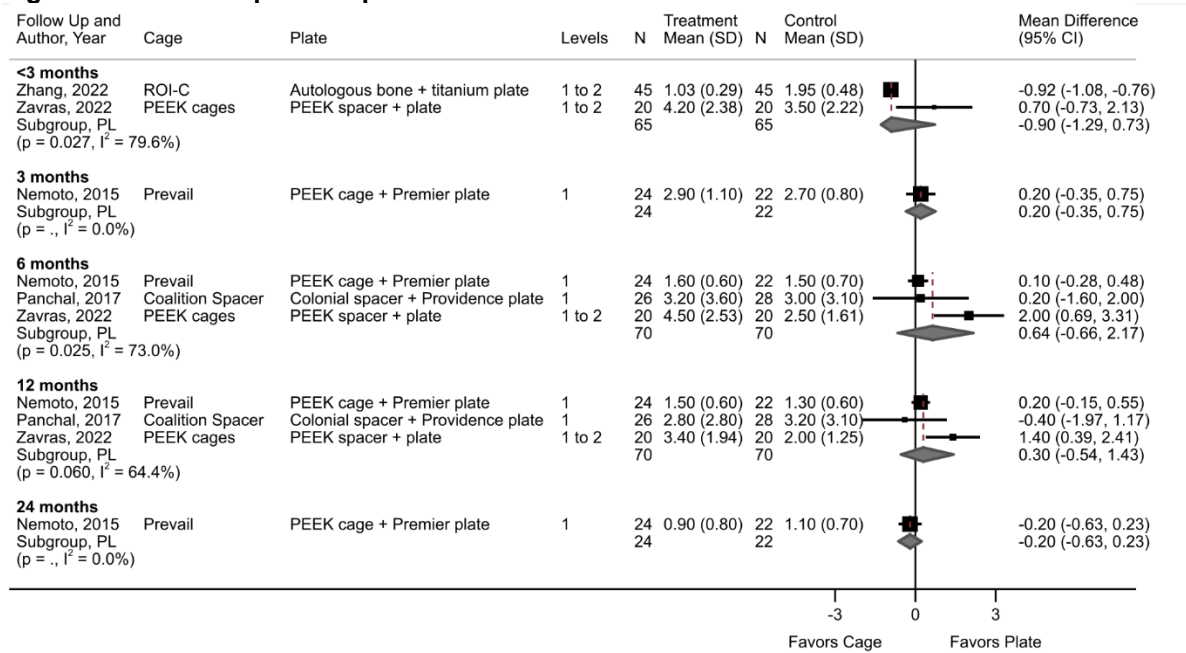
There was low-strength evidence of no difference between standalone cages versus plate and cage on arm pain (SOE: Low), with inadequate evidence to determine the benefits and harms of the two approaches on neck pain (SOE: Insufficient).

Four RCTs (N=230) reported changes in overall pain (pain location not specified) or neck pain using a visual analogue scale (VAS: 0-10 or 0-100) across various followup times ranging from less than 3 months to 24 months (Figure 40). Although neck pain was moderately, though not statistically greater at less than 3 months (MD -0.90, 95% CI -1.29 to 0.73) with a plate and cage compared with a standalone cage, the opposite was true at 6 months, MD 0.64, 95% CI -0.66 to 2.17). When pooled analysis was limited to trials of single-level disease, there were no differences in neck pain between standalone cage and plate and cage (Appendix F, Figure F-6).

Four RCTs (N=186) reported changes in arm pain using a visual analogue scale (VAS: 0-10 or 0-100) across various followup times. There were no differences in arm pain after ACDF between use of a standalone cage and a plate and cage at any time point from less than 3 months (MD -0.24, 95% CI -1.55 to 1.12) to 24 months (MD 0.20, 95% CI -0.09 to 0.49) (Figure 41). When analyses were limited to trials of single-level disease, there remained no difference in arm pain between fusion methods (Appendix F, Figure F-7).

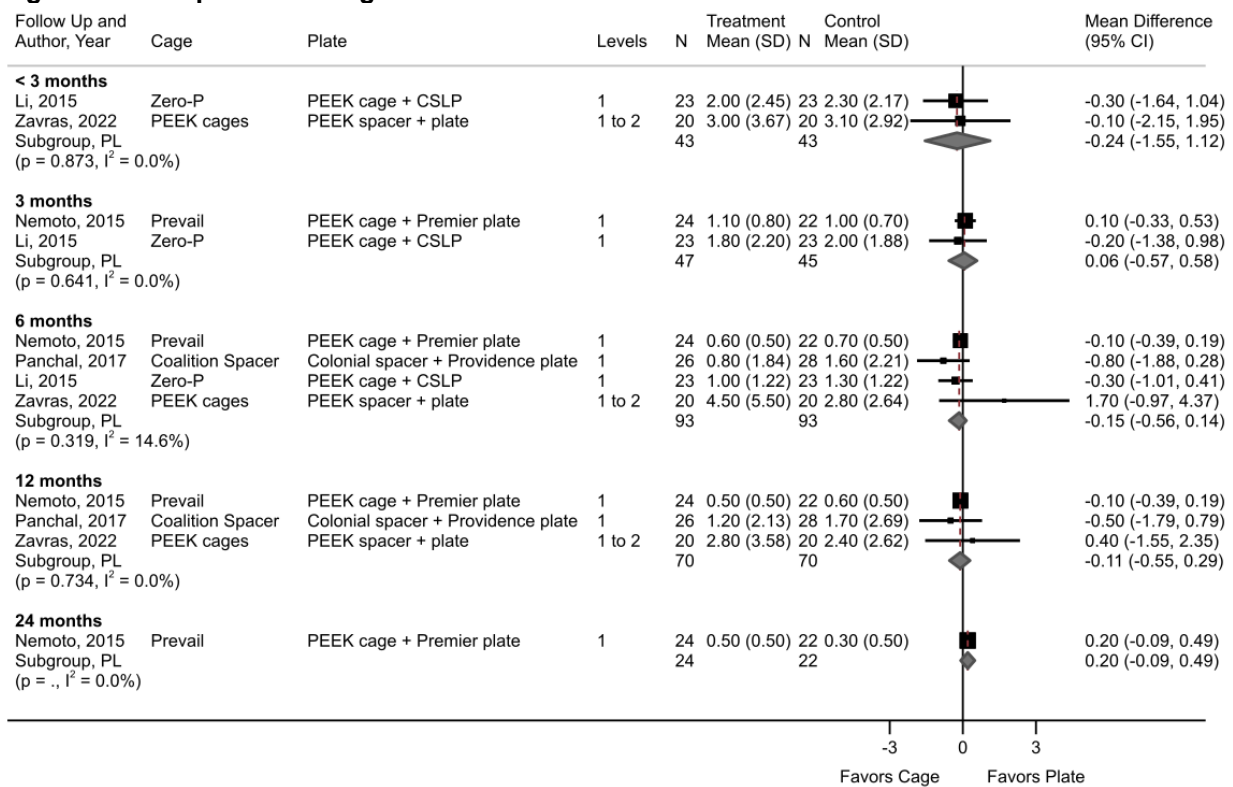
3.10 Results, Key Question 9

Figure 40. Neck/unspecified pain after ACDF



ACDF = anterior cervical discectomy and fusion; CI = confidence interval; PEEK = polyetheretherketone; PL = profile likelihood; ROI-C = ROI-C implant system; SD = standard deviation; Zero-P = zero-profile

Figure 41. Arm pain following ACDF



ACDF = anterior cervical discectomy and fusion; CI = confidence interval; CSLP = cervical spine locking plate; PEEK = polyetheretherketone; PL = profile likelihood; ROI-C = ROI-C implant system; SD = standard deviation; Zero-P = zero-profile

3.10 Results, Key Question 9

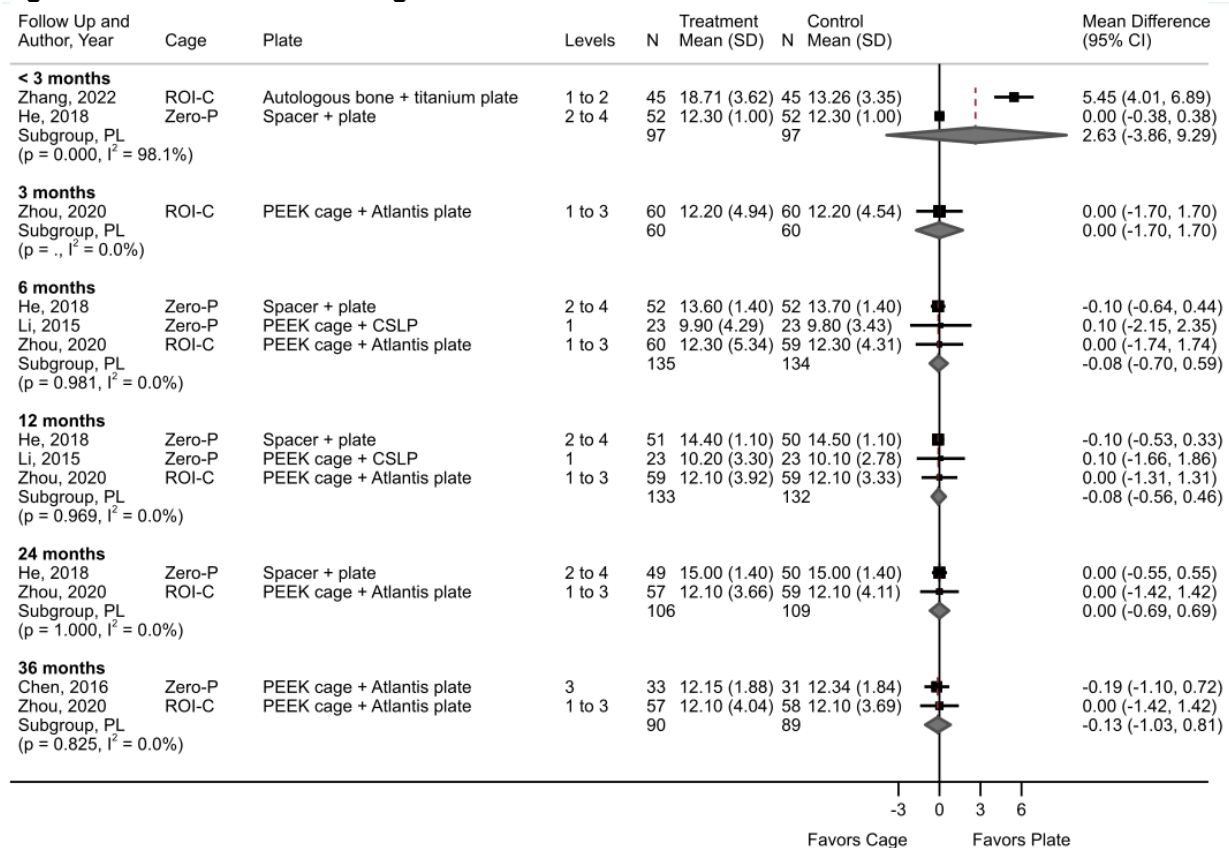
3.10.1.3.3 Function

3.10.1.3.3.1 Neurologic Function

There was low-strength evidence of no difference between standalone cages versus plate and cage in neurologic function (SOE: Low).

Five RCTs (N=424) reported changes on the JOA (lower score = worse disability, score 0 to 17) after ACDF using a standalone cage or a plate and cage (Figure 42). At less than 3 months, pooled analysis of two trials indicated moderately greater, although not statistically significant, JOA scores with a standalone cage versus a plate and cage (MD 2.63, 95% CI -3.86 to 9.29), this effect is driven by 1 of 2 trials, while the other trial found no effect. At longer followup times, there were no differences between treatments on JOA scores.

Figure 42. JOA scores following ACDF



ACDF = anterior cervical discectomy and fusion; CI = confidence interval; CSLP = cervical spine locking plate; JOA = Japanese Orthopaedic Association Scale; PEEK = polyetheretherketone; PL = profile likelihood; ROI-C = ROI-C implant system; SD = standard deviation; Zero-P = zero-profile

Note: Zhou, 2020 values are estimates from Figure 3 within the publication

3.10.1.3.3.2 General Function

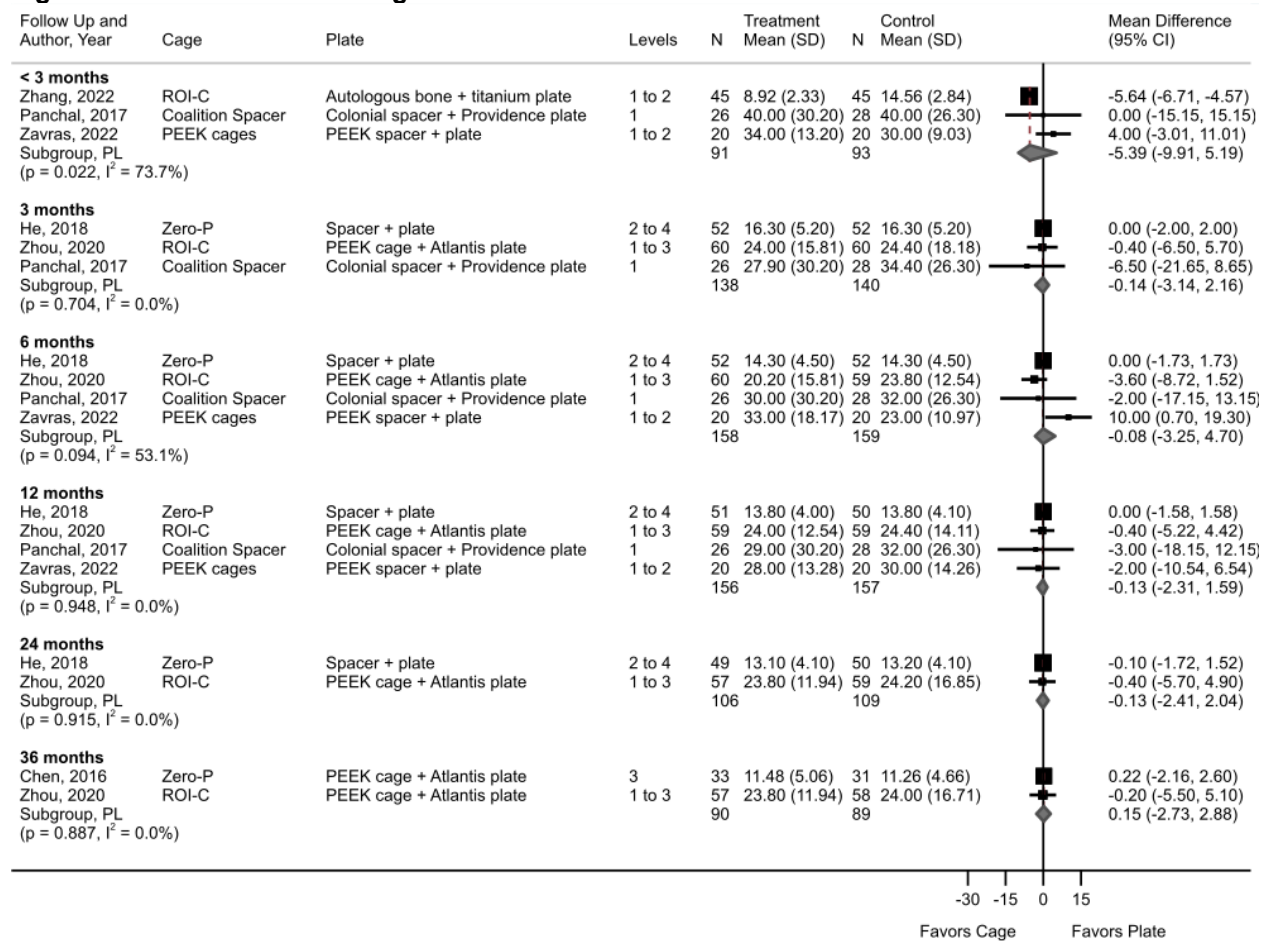
There was low-strength evidence of no difference between standalone cages versus plate and cage in general function (SOE: Low).

Six RCTs (N=472) reported changes on the NDI (higher score = worse disability, 0-50 raw score or 0% to 100%) following ACDF with either a standalone cage or a plate and cage (Figure 43). With the exception of less than 3 months timepoint, there were no differences between

3.10 Results, Key Question 9

ACDF with a standalone cage or plate and cage on NDI scores at other timepoints. At less than 3 months, study findings varied and although the pooled estimate slightly favors the standalone cage (MD -5.39, 95% CI -9.91 to 5.19), it is driven by the largest of the three studies and should interpreted with caution.

Figure 43. NDI scores following ACDF



ACDF = anterior cervical discectomy and fusion; CI = confidence interval; NDI = Neck Disability Index; PEEK = polyetheretherketone; PL = profile likelihood; ROI-C = ROI-C implant system; SD = standard deviation; Zero-P = zero-profile

Note: Zhou, 2020 values are estimates from Figure 2 within the publication

Additionally, one trial (N=41) reported no difference at 24 months between a standalone zero-profile device (Zero-P) and a plate and cage on the German version of the Neck Pain Disability Index (25.8% vs. 22.2%, p-value not reported).¹²⁵

One RCT (N=46) reported no difference between a standalone cage and plate and cage at 24 months on the Odom's criteria (Excellent: 46% vs. 55%; Good: 54% vs. 45%; Fair: 0% vs. 0%; Bad: 0% vs. 0%),¹³⁰ while another trial (N=41) reported the mean Odom's Criteria at 24 months was 3.2 with a standalone cage compared with 3.5 with plate and cage (p-value not reported).¹²⁵ A third trial (N=115) reported there were no differences between standalone cage versus plate and cage in ratings of "excellent" and "good" overall patient satisfaction (Excellent: 44% vs. 47%, p=0.763; Good: 33% vs. 29%, p=0.835; Fair: 23% vs. 24%, p=0.692; Poor: 0% vs. 0%, p=1.0) at 36 months.¹²⁴

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3.10.1.3.4 Quality of Life

There was low-strength evidence of no difference between standalone cages versus plate and cage in quality of life (SOE: Low).

One RCT (N=40) reported no differences in quality of life as assessed with the Veteran's RAND 12-Item Health Survey between treatment with a standalone cage versus a plate and cage at 6 weeks and at 12 months, although participants treated with a standalone cage reported better scores at 6 months postoperatively (38.38 vs. 26.27, $p=0.033$).¹³²

Five RCTs (N=253) assessed swallowing before and after treatment with a standalone cage versus a plate and cage with mixed results.^{125-128,132} Two trials used the Swallowing Quality of Life questionnaire,^{127,132} two trials rated severity of dysphagia symptoms as "None", "Mild", "Moderate", and "Severe"^{125,128} and one trial used the Eating Assessment Tool.¹²⁶ No trial reported differences in dysphagia scores between treatments beyond 3 months postoperatively. One trial reported worse dysphagia scores with plate and cage immediately postoperatively, at 1 month, and at 3 months but no difference at 12 months.¹²⁸ Another trial reported worse scores with plate and cage at 6 weeks but no differences at 6 and 12 months.¹³² There were no differences between dysphagia scores at any time from the postoperative period to 12 month in one RCT¹²⁶ and no differences at 36 months (only time reported) in another trial.¹²⁷ One trial reported no patient rated dysphagia as "moderate" or "severe" with either treatment¹²⁵ and no study reported that dysphagia required medical intervention (e.g., return to the operating room, percutaneous endoscopic gastrostomy tube placement).

One RCT (N=54) rated high risk of bias found no differences on the Voice Handicap Index between treatment with a standalone cage versus plate and cage from discharge to 12 months.¹²⁶

3.10.1.3.5 Harms

There was low-strength evidence of no difference between standalone cage versus plate and cage on adjacent-level ossification (SOE: Low), while evidence for subsidence and other adverse events was inadequate (SOE: Insufficient).

Seven RCTs (N=518) reported adverse events.^{124,127-132} Three trials reported substantially less adjacent-level ossification development with a standalone cage than with plate and cage (N=239, 8% vs. 27%, RR 0.25, 95% CI 0.12 to 0.52, $I^2=8\%$). The change in adjacent-level ossification development severity grade (0=no ossification, 3=severe ossification) was reported in one study and favored treatment with the standalone cage (0.208 vs. 0.818, $p=0.001$).¹³⁰ (SOE: Low) However, no patient required reoperation at 36 months in two trials;^{124,127} reoperation rates were not reported in the third trial.¹³⁰

One RCT (N=46) reported a small, but not statistically significant difference in subsidence (loss of disc height) rates with a standalone cage compared with a plate and cage at 12 months (12.5% vs. 9.1%, RR 1.38, 95% CI 0.25 to 7.48) and at 24 months (16.7% vs. 13.6%, RR 1.22, 95% CI 0.31 to 4.87).¹³⁰

One trial (N=104) reported few total complications (N=11) in 24 months that included one nerve injury (2%) and no cerebrospinal fluid leaks (0%) with the standalone cage compared with two nerve injuries (4%) and one cerebrospinal fluid leak (2%) with the plate and cage ($p=0.999$; $p=1.00$, respectively).¹²⁹ One trial (N=90) reported one (2%) incidence of loosening of the internally fixed implant with the standalone cage versus three (7%) with plate and cage ($p=0.333$).¹³¹ Another trial (N=40) reported participant treated with a standalone cage experienced a screw loosening, interbody subsidence, and C-5 fracture with revision surgery under consideration at trial publication.¹³² The same trial also reported one participant treated

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with a plate and cage experienced screw fracture, pseudarthrosis and underwent posterior fusion and decompression 14 months after the primary surgery.

3.10.2 Titanium Versus PEEK Cages

3.10.2.1 Key Findings

- There was low-strength of greater likelihood of fusion with a PEEK cage compared with a titanium or titanium-coated PEEK cage (SOE: Low).
- There was low-strength evidence of greater likelihood of improved general function with a PEEK cage versus a titanium cage (SOE: Low); evidence for neurologic function was inadequate (SOE: Insufficient).
- Evidence for subsidence and other adverse events was inadequate (SOE: Insufficient).

3.10.2.2 Description of Included Studies

Three RCTs (N=217) compared ACDF using a titanium cage or titanium covered PEEK cage versus a PEEK cage.¹³³⁻¹³⁵ (Appendix C) The average study mean duration of followup was 45 months (range 12 months to 99.7 months). One study each was conducted in China, Taiwan, and Poland.

The average study mean age of participants was 50 years (range 46 years to 52 years); the average proportion of female participants was 49 and 45 percent, with one trial reporting that 72 percent of 170 disc spaces belonged to women. Two RCTs reported radiculopathy was experienced by 3 and 75 percent, myelopathy by 11 and 57 percent, and myeloradiculopathy by 13 and 40 percent.^{133,134} The third trial did not report myeloradiculopathy symptoms. One trial enrolled participants with 1-level (66%) or 2-level (34%) disease,¹³⁴ 3-level disease¹³³ or disease at 1 or more levels¹³⁵

All studies were rated moderate risk of bias (Appendix D). Methodological limitations included unclear randomization techniques, unclear blinding, and lack of intention to treat analysis. No funds were received in one trial¹³³ and funding was not reported in the other two. Evidence for neurologic function was rated insufficient due to limited evidence from one small trial. Evidence for subsidence was rated insufficient due to conflicting findings, while evidence for other harms was insufficient due to few adverse events (Appendix G).

3.10.2.3 Detailed Analysis

3.10.2.3.1 Fusion

There was low-strength evidence of a greater likelihood of fusion with a PEEK cage compared with a titanium or titanium-coated PEEK cage (SOE: Low)

Three RCTs (N=217) reported ACDF fusion rates at different followup times that were not different between titanium and PEEK cages or that favored PEEK cages.

One trial reported that at a mean of 99.7 months (range 86 to 116 months) all participants (N=60) achieved fusion of their 3-level disease with both the titanium cage and with the PEEK cage (87/87 levels vs. 93/93 levels).¹³³ However, followup was not available for 25 percent of the original participants. A second trial (N=53) reported a lower likelihood of fusion with the titanium cage (32/37 levels, 86.5%) versus the PEEK cages (34/34 levels, 100%, p=0.0335) after 24 months.¹³⁴ The third RCT (N=104) reported a large difference in the likelihood of complete

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fusion that favored the PEEK cage with complete fusion achieved in 26 of 59 titanium-covered PEEK cages implanted (44.1%) compared with 75 of 85 PEEK cages implanted (88.2%) at 12 months ($p < 0.001$).¹³⁵ Partial fusion was achieved by 55.9 percent of participants with titanium-covered PEEK cages and 11.76 percent of participants with PEEK cages.¹³⁵ There were no instances of an absence of fusion.¹³⁵

3.10.2.3.2 Function

3.10.2.3.2.1 Neurologic Function

There was inadequate evidence of the benefits and harms of PEEK cage versus titanium cage on neurologic function (SOE: Insufficient).

One RCT (N=60) found JOA scores improved from baseline (baseline: 9.6 vs. 9.8) with both a titanium implant and a PEEK implant, but improvement was moderately greater with the PEEK implant (12.8 vs. 14.2, endpoint difference: -1.4, 95% CI -2.33 to -0.47).¹³³

3.10.2.3.2.2 General Function

There was low-strength evidence of improved general function with a PEEK cage compared to a titanium cage (SOE: Low).

The same trial above (N=60) also found moderately improved NDI scores from baseline (baseline: 36.2 vs. 35.4) with both the titanium and the PEEK implant, but improvement was greater with the PEEK implant (21.6 vs. 15.2, endpoint difference: 6.4, 95% CI 5.13 to 7.67).¹³³

Two RCTs (N=113) reported results on Odom's criteria that favored PEEK cages, although differences were not statistically significant in one trial.^{133,134} One trial (N=60) reported moderately worse clinical status according to Odom's criteria with the titanium cage versus the PEEK cage (Excellent: 24% vs. 35%; Good: 31% vs. 39%; Fair: 28% vs. 16%; Bad: 17% vs. 10%, $p < 0.05$).¹³³ One trial (N=53) reported no difference between treatments on clinical status (Excellent: 21% vs. 28%; Good: 54% vs. 52%; Fair: 14% vs. 8%; Poor: 11% vs. 12% or successful treatment: 75% vs. 80%, $p = 0.6642$).¹³⁴ In the trial where enrollment was limited to individuals with 3-level disease, treatment with the PEEK cage was associated with better clinical status, whereas in the trial of 1- and 2-level disease, there was no differences between cage materials on perceived improvement. Additionally, the followup times were greatly different between trials (99.7 months vs. 24 months) with the longer followup time associated with better ratings.

3.10.2.3.3 Quality of Life

No studies reported quality of life outcomes.

3.10.2.3.4 Harms

Evidence was inadequate to determine the effect of a PEEK cage versus a titanium cage on subsidence or other adverse events (SOE: Insufficient).

One RCT (N=104) found no difference between a titanium-coated PEEK implant and a PEEK implant on the incidence of subsidence in 166 levels (20.6% vs. 21.4%, $p = 0.875$).¹³⁵ However, subsidence was reported with 34.5% of titanium cages (87 levels) compared with 5.4% of PEEK cages (93 levels) in a second RCT (N=60, $p < 0.05$)¹³³ and 16.2% of 37 levels versus 0% of 34 levels in a third RCT (N=53, $p < 0.001$).¹³⁴ All three trials defined subsidence similarly (≥ 3 mm of interspace collapse). It is unclear the reason for the difference in study findings; possibilities include the cage materials (a titanium-coated PEEK cage may perform differently

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than a titanium cage) and the duration since ACDF (12 months in the trial that found no difference versus 24 months and 99.7 months in the other two trials) (SOE: Insufficient).

One RCT (N=53) reported that after 24 months, there were no neurovascular injuries and no revision surgeries with either the titanium cage or the PEEK cage, but that one patient, who received the titanium cage, experienced a hematoma that was removed the day after surgery.¹³⁴ One RCT (N=60) reported that at a mean of 99.7 months two patients treated with a titanium cage experienced cage dislocation but were asymptomatic.¹³³

3.10.3 Autograft, Allograft, and Other Osteogenic Materials

3.10.3.1 Key Findings

- There was inadequate evidence to determine comparative benefits (fusion, pain reduction, improved function, improved quality of life) for any osteogenic material versus any other osteogenic material (SOE: Insufficient).
- There was low-strength evidence that the use of bone morphogenetic protein 2 (BMP-2) in the cervical spine was associated with increased complications compared to no BMP-2 (SOE: Low); evidence was inadequate to determine the comparative harms of other osteogenic materials (SOE: Insufficient).

3.10.3.2 Description of Included Studies

Six RCTs (N=637) compared autologous bone graft, allograft, and/or other materials to support fusion in ACDF (Appendix C).¹³⁶⁻¹⁴¹ The average mean followup duration was 17 months (range 6 months to 24 months). Two trials were conducted in the United States, two in China, and one each in South Korea and India.

The average study sample size was 106 (range 32 to 319); the average study mean age was 49 years (range 43 years to 55 years). One trial did not report age of participants.¹³⁹ The mean proportion of females enrolled was 52 percent (range 30% to 66%). The average proportion of patients with radiculopathy was 61 percent (range 28% to 100%), the average proportion of patients with myelopathy was 21 percent (range 0% to 38%), and the average proportion of patients with myeloradiculopathy was 18 percent (range 0% to 34%). One trial reported that all study participants had radiculopathy, myelopathy or both.¹⁴⁰ All participants enrolled had 1-level degenerative disease,^{137,141} 1- to 2-level disease^{136,138,140} or 1- to 3-level disease.¹³⁹

Additionally, two NRSI (N=944) assessed heterotopic ossification and complications due to neck swelling with the use of BMP-2 compared to anterior cervical fusion without BMP-2.^{142,143} The mean age in one NRSI was 51 years with 51 percent female and 24 percent of study participants having myelopathy and 1 or more levels fused.¹⁴³ The other nonrandomized study, which took data from multiple investigational device exemption trials, did not report aggregate baseline patient characteristics but used propensity scoring on 28 predefined demographic and preoperative variables.¹⁴²

One RCT was rated high risk of bias¹³⁹ and the remaining RCTs were rated moderate risk of bias (Appendix D). Methodological limitations included unclear randomization methods, unclear blinding, and unclear attrition. Both NRSIs were also rated moderate risk of bias and were downgraded due to baseline differences between study groups on prognostic variables and unclear blinding of outcome assessor. Two trials each reported industry funding, nonprofit funding, and grant funding; one trial did not address funding. One NRSI used data from three Investigational Device Exemption (IDE) trials,¹⁴² while the other reported no funds or support

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from industry.¹⁴³ Evidence comparing allograft, autograft, and other osteogenic materials on likelihood of fusion, pain improvement, function, and overall harms (with the exception of BMP-2 use) was rated insufficient due to limited evidence for each comparison (Appendix G).

3.10.3.3 Detailed Analysis

3.10.3.3.1 Fusion

There was inadequate evidence to determine the comparative benefits and harms of autograft, allograft, or other osteogenic material versus any other osteogenic material on fusion (SOE: Insufficient).

Six RCTs (N=534) assessed ACDF with autograft, allograft, or other materials (e.g., hydroxyapatite, calcium sulphate) and found no differences between materials in achievement of spinal fusion (Table 3). Fusion rates for all materials were high for all trials but only one randomized study was available for each comparison.

Table 3. Fusion with ACDF using various osteogenic materials

Trial (Timepoint)	Intervention A (Sample Size)	Intervention B (Sample Size)	Findings
Arnold, 2018 ¹³⁷ (24 months)	i-Factor + allograft ring (N=117)	Local graft + allograft ring (N=127)	97.30% vs. 94.44%, p=0.2513
Baskin, 2003 ¹⁴⁰ (24 months)	BMP-2 + allograft ring (N=10)	ICBG + allograft ring (N=10)	100% vs. 100%, p=1.0
Cho, 2005 ¹³⁹ (6 months)	Biphasic calcium phosphate ceramic + PEEK cage (N=50)	ICBG + PEEK cage (N=50)	100% vs. 100%, p=1.0
Kanna, 2021 ¹³⁶ (12 months)	Allograft + patient's blood + titanium cage (N=13)	Local graft + titanium cage (N=14)	100% vs. 100%, p=1.0 <u>Fusion grade: (p=0.73)</u> F: 23.2% vs. 28.6% F+: 38.4% vs. 42.8% F++: 38.4% vs. 28.6%
Xie, 2015 ¹³⁸ (12 months) (24 months)	Calcium sulphate + demineralized bone matrix + PEEK cage (N=34)	Autogenous iliac cancellous bone + PEEK cage (N=32)	<u>12 months 104 levels, 24 months levels NR:</u> 12 months: 94.3% vs. 100%, p=NR 24 months: 100% vs. 100%, p=1.0
Yi, 2015 ¹⁴¹ (12 months)	Hydroxyapatite + demineralized bone matrix + PEEK cage (N=38)	B-tricalcium phosphate + hydroxyapatite + PEEK cage (N=39)	<u>X-ray: 87% vs. 87%, p=1.0</u> <u>CT: 87% vs. 72%, p=0.16</u>

ACDF = anterior cervical discectomy and fusion; BMP-2 = bone morphogenetic protein; CT = computed tomography; ICBG = iliac crest bone graft; i-Factor = biologic bone graft made of a small peptide bound to an anorganic bone mineral; NR = not reported; PEEK = polyetheretherketone

3.10.3.3.2 Pain

There was inadequate evidence to determine the comparative benefits and harms of autograft, allograft, or other osteogenic material versus any other osteogenic material on neck or arm pain (SOE: Insufficient).

Five RCTs (N=440) assessed neck and arm pain using a VAS or a numerical (pain) rating scale (Tables 4 and 5). One small trial (N=27) reported a moderately greater decrease in neck pain 12 months after ACDF with a local graft and titanium cage than with allograft and titanium cage (MD -6.15 vs. -5.09, p<0.05).¹³⁶ Another trial (N=20) found a moderate, though not statistically significant, improvement in neck pain with BMP-2 and allograft ring versus iliac

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crest bone graft and an allograft ring on a 20-point numerical rating scale (MD 13.0 vs. MD 9.0, $p > 0.05$).¹⁴⁰

One trial (N=27) also found a substantially greater decrease in arm pain with local graft and a titanium cage compared with allograft and the same cage (MD -7.24 vs. MD -4.55, $p < 0.05$)¹³⁶ (Table 5). However, these results should be interpreted with caution due to the trial's small sample size. One RCT (N=26) reported a substantially greater reduction in arm pain at 24 months with BMP-2 and allograft ring compared with iliac crest bone graft and allograft ring on a 20-point numerical rating scale (-14 vs. -8.5, $p < 0.03$).¹⁴⁰ However, as above, these results should be interpreted with caution due to the small sample size. One RCT (N=244) found that ACDF with i-Factor (bone graft made of a peptide bound to an inorganic bone mineral) and an allograft ring was associated with improved VAS arm pain scores at 24 months (1.56 vs. 1.95, $p = 0.0306$) compared with local graft and an allograft ring.¹³⁷ However, this small difference in scores is below the threshold for a small effect and may not be clinically meaningful. One RCT (N=77) found a small, although not statistically significant, improvement in arm pain at 12 months with hydroxyapatite, demineralized bone matrix and a PEEK cage compared with β -tricalcium phosphate, hydroxyapatite and a PEEK cage (VAS: MD -4.2 vs. MD -3.6, $p = 0.27$).¹⁴¹

There were no differences in neck or arm pain with other comparisons.

Table 4. Neck pain with ACDF using various osteogenic materials

Trial (Timepoint)	Intervention A (Sample Size)	Intervention B (Sample Size)	Findings
Arnold, 2018 ¹³⁷ (24 months)	i-Factor + allograft ring (N=117)	Local graft + allograft ring (N=127)	VAS endpoint: 1.79, 95% CI 1.33 to 2.24 vs. 2.25, 95% CI 1.78 to 2.72, $p = 0.4619$
Baskin, 2003 (24 months) ¹⁴⁰	BMP-2 + allograft ring (N=14)	ICBG + allograft ring (N=12)	20-point NRS: MD 13.0 vs. MD 9.0, $p > 0.05$
Kanna, 2021 ¹³⁶ (12 months)	Allograft + patient's blood + titanium cage (N=13)	Local graft + titanium cage (N=14)	0-10 NPRS: MD -5.09 vs. MD -6.15, $p < 0.05$
Xie, 2015 ¹³⁸ (24 months)	Calcium sulphate + demineralized bone matrix + PEEK cage (N=34)	Autogenous iliac cancellous bone + PEEK cage (N=32)	Improved VAS neck pain: 69% vs. 68%, $p > 0.05$
Yi, 2015 ¹⁴¹ (12 months)	Hydroxyapatite + demineralized bone matrix + PEEK cage (N=38)	B-tricalcium phosphate + hydroxyapatite + PEEK cage (N=39)	VAS: MD -1.6 vs. -1.8, $p = 0.82$

ACDF = anterior cervical discectomy and fusion; BMP-2 = bone morphogenetic protein; CI = confidence interval; ICBG = iliac crest bone graft; i-Factor = biologic bone graft made of a small peptide bound to an anorganic bone mineral; MD = mean difference; N(P)RS = Numeric Pain Rating scale; PEEK = polyetheretherketone; VAS = visual analogue scale

Table 5. Arm pain with ACDF using various osteogenic materials

Trial (Timepoint)	Intervention A (Sample Size)	Intervention B (Sample Size)	Findings
Arnold, 2018 ¹³⁷ (24 months)	i-Factor + allograft ring (N=117)	Local graft + allograft ring (N=127)	VAS endpoint: 1.56, 95% CI 1.06 to 2.05 vs. 1.95, 95% CI 1.51 to 2.39, $p = 0.0306$
Baskin, 2003 ¹⁴⁰ (24 months)	BMP-2 + allograft ring (N=14)	ICBG + allograft ring (N=12)	20-point NRS: MD -14.0 vs. -8.5, $p < 0.03$
Kanna, 2021 ¹³⁶ (12 months)	Allograft + patient's blood + titanium cage (N=13)	Local graft + titanium cage (N=14)	0-10 NPRS: MD -4.55 vs. -7.24, $p < 0.05$

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Trial (Timepoint)	Intervention A (Sample Size)	Intervention B (Sample Size)	Findings
Xie, 2015 ¹³⁸ (24 months)	Calcium sulphate + demineralized bone matrix + PEEK cage (N=34)	Autogenous iliac cancellous bone + PEEK cage (N=32)	Improved VAS arm pain: 70% vs. 68%, p>0.05
Yi, 2015 ¹⁴¹ (12 months)	Hydroxyapatite + demineralized bone matrix + PEEK cage (N=38)	B-tricalcium phosphate + hydroxyapatite + PEEK cage (N=39)	VAS: MD -4.2 vs. -3.6, p=0.27

ACDF = anterior cervical discectomy and fusion; BMP-2 = bone morphogenetic protein; CI = confidence interval; ICBG = iliac crest bone graft; i-Factor = biologic bone graft made of a small peptide bound to an anorganic bone mineral; MD = mean difference; N(P)RS = Numeric Pain Rating scale; PEEK = polyetheretherketone; VAS = visual analogue scale

3.10.3.3.3 Function

3.10.3.3.3.1 Neurologic Function

There was inadequate evidence to determine the comparative benefits and harms of autograft, allograft, or other osteogenic material versus any other osteogenic material on neurologic function (SOE: Insufficient).

Four RCTs (N=436) reported changes in neurological status after ACDF (Table 6). One trial (N=100) found no differences between use of biphasic calcium phosphate ceramic plus a PEEK cage compared with iliac crest bone graft plus a peek cage on JOA score, or JOA recovery rate at 6 months post ACDF.¹³⁹ One trial (N=66) reported no difference between calcium sulphate plus demineralized bone matrix plus a PEEK cage versus autogenous iliac cancellous bone plus a PEEK cage in JOA scores at 24 months.¹³⁸ One trial (N=26) reported neurologic success (i.e., maintenance or improvement in sensory and motor function) in all remaining participants at 24 months,¹⁴⁰ while another trial (N=244) reported that almost all participants (94.87% vs. 93.70%) experienced neurologic success, also at 24 months.¹³⁷

Table 6. Neurologic function with ACDF using various osteogenic materials

Trial (Timepoint)	Intervention A (Sample Size)	Intervention B (Sample Size)	Findings
Arnold, 2018 ¹³⁷ (24 months)	i-Factor + allograft ring (N=117)	Local graft + allograft ring (N=127)	Neurologic success: 94.87% vs. 93.70%, p=0.6944
Baskin, 2003 ¹⁴⁰ (24 months)	BMP-2 + allograft ring (N=14)	ICBG + allograft ring (N=12)	Neurologic success: 100% vs. 100%, p=1.0
Cho, 2005 ¹³⁹ (6 months)	Biphasic calcium phosphate ceramic + PEEK cage (N=50)	ICBG + PEEK cage (N=50)	JOA score: MD 2.84 vs. 2.48, p=0.17 JOA recovery rate: 86.51% vs. 83.48%, p=0.22
Xie, 2015 ¹³⁸ (24 months)	Calcium sulphate + demineralized bone matrix + PEEK cage (N=34)	Autogenous iliac cancellous bone + PEEK cage (N=32)	JOA score: MD 3.62 vs. 3.22, p>0.05

ACDF = anterior cervical discectomy and fusion; BMP-2 = bone morphogenetic protein; ICBG = iliac crest bone graft; i-Factor = biologic bone graft made of a small peptide bound to an anorganic bone mineral; JOA = Japanese Orthopaedic Association; MD = mean difference; PEEK = polyetheretherketone

3.10.3.3.3.2 General Function

There was inadequate evidence to determine the comparative benefits and harms of autograft, allograft, or other osteogenic material versus any other osteogenic material on general function (SOE: Insufficient).

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Four RCTs (N=374) assessed post ACDF neck disability with the NDI (Table 7). One RCT (N=244) found that treatment with i-Factor plus an allograft ring in ACDF resulted in slightly, though not statistically significant, improvement on NDI endpoint scores at 24 months compared with local graft and allograft ring (22.33 vs. 25.66, p=0.5607).¹³⁷ One small trial (N=26) reported moderately greater improvement on the NDI after 24 months with BMP-2 and allograft ring compared with iliac crest bone graft and allograft ring (52.7 vs. 36.9, p<0.03).¹⁴⁰ Another small trial (N=27) reported moderately greater improvement on NDI scores after 12 months with local graft plus a titanium cage versus allograft plus titanium cage (MD 56.5 vs. MD 41.4, p<0.05).¹³⁶ There was no difference in improvement in NDI scores with hydroxyapatite/demineralize bone matrix plus PEEK cage versus β -tricalcium phosphate/hydroxyapatite plus PEEK cage at 12 months.¹⁴¹

Three RCTs (N=357) assessed general function using the SF-36 or the 2-item SF-12 (Table 7). Two trials found no difference in function on the SF-36 after ACDF using an allograft ring with either i-Factor or local graft¹³⁷ or using an allograft with either BMP-2 or an iliac crest bone graft.¹⁴⁰ One small trial (N=27) reported moderately better function at 12 months using the 2-item SF-12 with local graft plus a titanium cage compared with the same cage and allograft infused with the participant's blood (MD 48.7 vs. 65.9, p<0.05).¹³⁶ However, care should be used in interpreting these results due to the small study sample size.

Table 7. General function with ACDF using various osteogenic materials

Trial (Timepoint)	Intervention A (Sample Size)	Intervention B (Sample Size)	Findings
Arnold, 2018 ¹³⁷ (24 months)	i-Factor + allograft ring (N=117)	Local graft + allograft ring (N=127)	NDI endpoint: 22.33, 95% CI 18.90 to 25.76 vs. 25.66, 95% CI 22.55 to 28.78, p=0.5607
Baskin, 2003 ¹⁴⁰ (24 months)	BMP-2 + allograft ring (N=14)	ICBG + allograft ring (N=12)	NDI improvement from preoperative scores: 52.7 vs. 36.9, p<0.03
Kanna, 2021 ¹³⁶ (12 months)	Allograft + patient's blood + titanium cage (N=13)	Local graft + titanium cage (N=14)	NDI: MD 41.4 vs. MD 56.5, p<0.05
Yi, 2015 ¹⁴¹ (12 months)	Hydroxyapatite + demineralized bone matrix + PEEK cage (N=38)	B-tricalcium phosphate + hydroxyapatite + PEEK cage (N=39)	NDI: MD 22 vs. MD 20, p=0.62
Arnold, 2018 ¹³⁷ (24 months)	i-Factor + allograft ring (N=117)	Local graft + allograft ring (N=127)	SF-36 PCS endpoint: 45.40, 95% CI 43.60 to 47.20 vs. 44.47, 95% CI 42.70 to 46.24, p=0.6461 SF-36 MCS endpoint: 48.43, 95% CI 46.43 to 50.44 vs. 48.41, 95% CI 46.42 to 50.40, p=0.9040
Baskin, 2003 ¹⁴⁰ (24 months)	BMP-2 + allograft ring (N=14)	ICBG + allograft ring (N=12)	SF-36 PCS: MD 16.7 vs. MD 14.7, p>0.05 SF-36 MCS: MD 21.8 vs. MD 7.2, p>0.05
Kanna, 2021 ¹³⁶ (12 months)	Allograft + patient's blood + titanium cage (N=13)	Local graft + titanium cage (N=14)	2-item SF-12: MD 48.7 vs. MD 65.9, p<0.05

ACDF = anterior cervical discectomy and fusion; BMP-2 = bone morphogenetic protein; CI = confidence interval; ICBG = iliac crest bone graft; i-Factor = biologic bone graft made of a small peptide bound to an anorganic bone mineral; MCS = mental component summary score; MD = mean difference; NDI = Neck Disability Index; PCS = physical component summary score; PEEK = polyetheretherketone; SF-12 = 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey

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3.10.3.3.4 Harms

There was low-strength evidence that the use of BMP-2 in cervical spine fusion is associated with increased complications compared to the use of no BMP-2 (SOE: Low), while evidence was inadequate to determine the comparative harms of other osteogenic materials (SOE: Insufficient).

Four RCTs (N=520) and 2 NRSI studies (N=944) reported harms with ACDF using various graft materials (Table 8). There were few differences between treatments reported in the RCTs in the likelihood of various harms. One trial (N=319) reported a moderately greater likelihood of experiencing a new radiculopathy with an allograft ring with local graft than with i-Factor (13.66% vs. 25.00%, p=0.0142) but there were no differences in new intractable neck pain or progression of neuropathy.¹³⁷ One trial (N=100) reported a shorter hospital stay with a biphasic calcium phosphate ceramic combined with a PEEK cage compared with a PEEK cage with iliac crest bone graft.¹³⁹ Reasons for the difference in hospital stay were not provided.

Two retrospective NRSI of BMP-2 compared with no BMP-2 in ACDF (N=944) reported a greater likelihood of heterotopic ossification (78.6% vs. 59.2%, p<0.001)¹⁴² and complications associated with neck swelling¹⁴³ with the use of BMP-2 (Table 8). In one NRSI, participants were 10 times more likely to have a neck swelling complication if BMP-2 was used in anterior cervical fusion, even after controlling for potential confounding variables (e.g., age, gender, presence of myelopathy, levels fused, smoking).¹⁴³

Table 8. Adverse events with ACDF using various graft materials

Trial (Timepoint)	Intervention A (Sample Size)	Intervention B (Sample Size)	Findings
Arnold, 2018 ¹³⁷ (24 months)	i-Factor + allograft ring (N=165)	Local graft + allograft ring (N=154)	Pseudarthrosis: 12.73% vs. 16.23%, p=0.3790 New intractable neck pain: 44.72% vs. 42.11%, p=0.1149 New radiculopathy: 13.66% vs. 25.00%, p=0.0142 Adjacent segment degeneration: 13.04% vs. 16.45%, p=0.4274 Retropharyngeal hematoma/airway obstruction: 0% vs. 0.66%, p=0.4856 Progression of myelopathy: 0.62% vs. 0%, p=1.0 Additional cervical spine surgery: 7.45% vs. 10.53%, p=0.34
Baskin, 2003 ¹⁴⁰ (24 months)	BMP-2 + allograft ring (N=18)	ICBG + allograft ring (N=15)	Additional cervical spine surgery: 5.6% vs. 0%, p>0.05
Cho, 2005 ¹³⁹ (6 months)	Biphasic calcium phosphate ceramic + PEEK cage (N=50)	ICBG + PEEK cage (N=50)	Hospital stay (days): 4.43 vs. 7.00, p=0.02
Xie, 2015 ¹³⁸ (24 months)	Calcium sulphate + demineralized bone matrix + PEEK cage (N=35)	Autogenous iliac cancellous bone + PEEK cage (N=33)	Major complications: 0% vs. 0%, p=1.0 Additional cervical spine surgery: 0% vs. 0%, p=1.0
Arnold, 2016 ¹⁴² (Retrospective; used propensity scoring)	BMP-2 + PEEK cage + titanium plate (N=224)	Cortical allograft ring + local bone + Atlantis Plate (N=486)	Heterotopic ossification 24 months postoperatively: 78.6% vs. 59.2%, p<0.001

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Smucker, 2006 ¹⁴³ (Retrospective: adjusted for potential confounders)	BMP-2 (N=69)	No BMP-2 (N=165)	Neck swelling complications: 27.5% vs. 3.6%, p<0.001 Delay in discharge: 13% vs. 3%, p=NR Severe dysphagia: 7% vs. 1%, p=NR Reintubation: 3% vs. 0%, p=NR PEG placement: 1% vs. 1%, p=NR Tracheostomy: 1% vs. 0.6%, p=NR Incision and drainage of swollen surgical site: 4% vs. 0%, p=NR Readmission to manage swelling: 3% vs. 0%, p=NR
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ACDF = anterior cervical discectomy and fusion; BMP-2 = bone morphogenetic protein; ICBG = iliac crest bone graft; i-Factor = biologic bone graft made of a small peptide bound to an anorganic bone mineral; NR = not reported; PEEK = polyetheretherketone; PEG = percutaneous endoscopic gastrostomy

3.11 Results, Key Question 10

3.11 Key Question 10: In patients with pseudarthrosis after prior anterior cervical fusion surgery, what are the comparative effectiveness and harms of posterior approaches compared to revision anterior arthrodesis?

No studies met eligibility criteria for Key Question 10.

3.12 Results, Key Question 11

3.12 Key Question 11: In patients with cervical spondylotic myelopathy, what is the prognostic utility of preoperative magnetic resonance imaging (MRI) findings for neurologic recovery after surgery?

3.12.1 Key Findings

- There was low-strength evidence that multisegmental T2-weighted-increased signal intensity (ISI) and sharp T2-weighted-ISI on preoperative MRI was associated with poorer outcomes (SOE: Low).
- There was low-strength evidence that increased signal intensity ratio (SIR) was associated with poorer neurologic recovery (SOE: Low).
- Evidence for other MRI findings was inadequate (SOE: Insufficient).

3.12.2 Description of Included Studies

MRI of the cervical spine is a common imaging procedure performed prior to cervical spine surgery. To identify whether MRI findings can predict neurologic recovery after surgery, we identified one relevant systematic review¹⁴⁴ (that included 22 studies) and 17 additional studies¹⁴⁵⁻¹⁶³ that were not included in the systematic review or published subsequent to the review's search dates that provided evidence for this question (Appendix C). Studies were conducted in the United States, China, Taiwan, United Kingdom, Spain, Italy, Greece, India, Korea, and Japan. Most studies were small, with sample sizes ranging from 19 to 861 (mean 162) participants. Mean age of participants ranged from 47 to 70 years (overall mean: 53.9 years), and the proportion of females ranged from 7 to 50 percent (mean 38%). The systematic review and 14 of the 17 primary studies were rated moderate risk of bias, with 3 studies rated high risk of bias (Appendix D). Evidence was insufficient for MRI findings other than ISI and SIR due to limited available data for other outcomes (Appendix G).

3.12.3 Detailed Analysis

3.12.3.1 Fusion

No studies reported fusion outcomes.

3.12.3.2 Pain

No studies reported pain outcomes.

3.12.3.3 Function

3.12.3.3.1 Systematic Review Evidence

A 2013 systematic review that assessed the prognostic utility of preoperative MRI for neurologic recovery after surgery included 22 studies (N=1,508).¹⁴⁴ The included studies evaluated preoperative MRI in patients undergoing cervical disc surgery using a posterior approach (k=7), ACDF (k=5), mixed approaches (k=9), or an unspecified procedures (k=1) over followup ranging from 1.5 to 60.6 months (mean 27.8; standard deviation 4.6 months). The majority of patients in the included studies were male (mean proportion of females: 27.1%), and the mean age (from 20 studies reporting age) was 57.4 (standard deviation, 1.0) years. Heterogeneity of study designs, methods, and outcomes (JOA in 17 studies, Nurick grade in 5

3.12 Results, Key Question 11

studies, NDI in one study, and Neurosurgical Cervical Spine Score in one study) of the included studies precluded pooling of study findings, and the mixed results were reported narratively. Presence of multisegmental T2-weighted increased signal intensity (ISI) was associated with worse functional outcomes in five studies, not associated with outcomes in four other studies, and lack of T2-weighted ISI was associated with better outcomes in three studies; qualitative classification of T2-weighted ISI was associated with poorer functional status in six studies, not associated with functional outcomes in one study, and lack of T2-weighted ISI associated with better outcomes in one study. Snake-eye appearance on axial T2-weighted MRI, ISI in gray and white matter, and increased SIR were associated with poorer surgical outcomes in one study each.

3.12.3.3.2 Primary Study Evidence

We identified four relevant studies (N=326) that were not included in the systematic review,^{156,157,159,160} as well as 13 studies (in 15 publications) that were published subsequent to the review search dates.^{145-155,158,161-163} Of these studies, two assessed presence of segmental abnormalities (endplate abnormalities, modic changes, and Cobb angle/loss of lordosis),^{146,147,152} six assessed qualitative differences in ISI intensity,^{145,149-151,154,157} three assessed SIR,^{148,153,155} one evaluated presence or absence of signal changes,¹⁵⁹ two evaluated diffusion tensor tractography grading,^{158,162} one (in 2 publications) evaluated diffusion-based spectrum imaging,^{161,162} one evaluated a radiomic-based extra tree model,¹⁶³ one evaluated the size of the transverse area at the compression site,¹⁶⁰ and one evaluated size, extent, and qualitative intensity.¹⁵¹ The study (N=55) that assessed the size of the transverse area reported significant associations with postoperative JOA scores ($r=0.298$) and with JOA recovery ($r=0.295$) (both $p<0.05$).¹⁶⁰ The study (N=56) that evaluated size, extent, and intensity of ISI reported no association of size or extent of ISI with functional outcomes;¹⁵¹ one other study of qualitative imaging signal intensity also reported no association of intensity changes with recovery (mJOA score ≥ 16 , RR 1.71; 95% CI 0.90 to 3.24),¹⁴⁵ while four studies (N=714) did find qualitative intensity associated with reduced recovery ratio, lower likelihood of optimal surgical outcome, or change in JOA or NDI scores.^{149-151,154} One study (N=52) reported improved JOA recovery rate (54.3% vs. 27.3%) in patients without ISI compared to those with ISI.¹⁵⁶ Another study (N=146) that assessed presence or absence of imaging signal changes reported that patients without imaging signal changes were more likely to have improvement in Nurick grade (OR 5.1; 95% CI, 1.87 to 25.1); however, there was no difference between patients without imaging signal changes and those with only T2-weighted signal changes.¹⁵⁹ Another study (N=73) found that the combination of T1-weighted hypointensity and T2-weighted hyperintensity was associated with poorer JOA recovery than T2-weighted hyperintensity alone or no ISI changes (JOA recovery 48% vs. 19% vs. 60.7%; T1- and T2-weighted ISI changes vs. T2-weighted ISI change only, $p=0.0259$).¹⁵⁷ Two studies of SIR (N=220) reported increased T2-weighted SIR associated with JOA recovery;^{148,155} one study (N=148)¹⁵³ reported no association between T2-weighted SIR and outcomes, while lower T1-weighted SIR was associated with poorer neurological outcomes assessed with the JOA. One study (N=129)¹⁵⁸ found that diffusion tensor tractography grading using MRI images was associated with JOA score changes ($r= -0.813$, $p<0.001$) and JOA recovery ($r= -0.429$, $p<0.001$), while conventional MRI ISI grading was associated with JOA score changes ($r= -0.674$, $p<0.001$) but not with JOA recovery ($r= -0.197$, $p=0.058$). However, another study (N=42) comparing diffusion-based spectrum imaging to diffusion tensor grading reported that no diffusion tensor metrics were associated with neurological (mJOA) or general

3.12 Results, Key Question 11

function (SF-36, NDI, and Myelopathy Disability Index) outcomes.¹⁶² The study found that preoperative diffusion-based spectrum imaging intra-axonal axial diffusivity and anisotropic fraction correlated with improved mJOA scores ($r=0.37$, $p=0.02$ and $r=0.34$, $p=0.03$, respectively).¹⁶² Another analysis of most of these same patients ($N=50$)¹⁶¹ compared diffusion-based spectrum imaging to clinical features and found greater prognostic utility with diffusion-based spectrum imaging (area under the curve [AUC] 75.3%) and the combination of diffusion-based spectrum imaging with clinical features (AUC 98.0%) than with assessment of clinical features alone (AUC 59.4%) for mJOA scores. The study reported similar findings for the prognostic utility of diffusion-based spectrum imaging (AUC 54.6%) or the combination of diffusion-based spectrum imaging and clinical features (AUC 65.3%) versus clinical features alone (AUC 48.8%) for NDI.

One study ($N=151$) evaluated a novel radiomic-based extra tree model of MRI data for predicting neurological outcomes following surgery for CSM.¹⁶³ The study reported that their radiomic-based model (AUC 75%) and the combination of their radiomic-based model with clinical assessment (AUC 71%) were superior to radiological assessment (AUC 43%) and the combination of radiological and clinical assessment (AUC 40%) for predicting neurologic recovery assessed using mJOA.

One study ($N=121$) reported a novel classification system for reporting loss of cervical lordosis following laminoplasty was predicted by an interplay of preoperative Cobb angle, T1 slope, and dynamic extension reserve.¹⁵² One study ($N=861$) reported Modic changes, defined as “subchondral vertebral bone marrow lesions of the endplate” on preoperative MRI and found that while modic changes were associated with greater postoperative disability, modic changes were also associated with older age, greater number of levels fused, and a longer duration of symptoms.¹⁴⁶

Comparing findings across studies was difficult due to the various study methods used (e.g., different type and basis of classification of T2 weighted ISI [single segment, multisegment, L2 classification, Q3 classification, SIR], different outcomes assessed [JOA, NDI, Nurick grade], and different methods to analyze the data [correlation, linear regression, multivariable regression, Student’s *t* test]). Preoperative MRI also preceded different types of surgery (e.g., ACDF, laminoplasty, posterior-anterior decompression), which reduces the generalizability of findings.

3.12.3.3.3 Synthesis of Systematic Review and Primary Study Findings

There was low-strength evidence that multisegmental T2-weighted-increase signal intensity and sharp T2-weighted-increased signal intensity on preoperative MRI was associated with poorer neurologic outcomes (SOE: Low); there was also low-strength evidence that increased SIR of preoperative MRI was associated with poorer neurologic recovery (SOE: Low)

In total, presence of ISI was associated with poorer neurologic outcomes (e.g., JOA recovery, Nurick grade, NDI) in 7 studies and absence of ISI was associated with better neurologic outcomes (e.g., JOA, Nurick grade) in 4 studies but was not associated with changes in neurologic outcomes in 5 studies. Qualitative grading (increased intensity) of ISI was associated with worse neurologic outcomes (e.g., JOA, NDI) in 11 studies, absence of T2-weighted intensity associated with a better neurologic outcome (Nurick grade) in 1 study, and not associated with neurologic outcomes in 3 studies. Higher SIR was associated with poorer recovery in 3 studies (AUCs ranged from 78.6% to 87.3% in the two studies that reported accuracy results); one study reported lower SIR on T1 weighted associated with poorer neurological outcomes (e.g., JOA), while T2-weighted SIR was not associated with outcomes.

3.12 Results, Key Question 11

One study reported that diffusion tensor tractography grading was more closely associated with neurological outcomes and recovery (e.g., JOA) than conventional ISI grading; however, another study found no association of diffusion tensor grading with neurological outcomes. One study of diffusion-based spectrum imaging found the imaging modality superior to diffusion tensor grading and assessment using clinical features. One study found a novel radiomic-based extra tree model to be superior to both radiological and clinical assessment (SOE for ISI and SIR: Low).

3.12.3.4 Quality of Life

No studies reported quality of life outcomes.

3.12.3.5 Harms

No studies reported harms or adverse events.

3.13 Results, Key Question 12

3.13 Key Question 12: What are the sensitivity and specificity of imaging assessment for identifying symptomatic pseudarthrosis after prior cervical fusion surgery?

3.13.1 Key Findings

- There is low-strength evidence that postoperative ACDF dynamic radiographs can predict pseudarthrosis in a largely asymptomatic population (SOE: Low) and a largely symptomatic population (SOE: Low).
- Evidence was inadequate for use of an angular method measurement in postoperative ACDF dynamic radiographs in predicting pseudarthrosis in an undefined population (SOE: Insufficient).

3.13.2 Description of Included Studies

Three nonrandomized studies (N=758)¹⁶⁴⁻¹⁶⁶ assessed diagnostic accuracy of radiographs in predicting pseudarthrosis after prior cervical fusion surgery (Appendix C). All studies were conducted in the United States. The mean ages of participants was 52 years; the proportion of females ranged from 42 to 62 percent. No studies reported race or ethnicity. In all studies, enrolled patients had undergone ACDF as the index surgery, and revision surgery included anterior or posterior approaches.

Two studies were rated moderate risk of bias^{164,165} and one high risk of bias¹⁶⁶ (Appendix D). Methodological limitations included lack of clarity on the number and characteristics of patients missing imaging studies; high attrition and lack of clarity on reference standard accuracy and assessor blinding. No studies reported receiving funding. Evidence for a novel measurement method in predicting pseudarthrosis was rated insufficient due to the small sample size, study quality, and reference standard (Appendix G).

3.13.3 Detailed Analysis

There is low-strength evidence that postoperative ACDF dynamic radiographs can predict pseudarthrosis in a largely asymptomatic and a largely symptomatic population (SOE: Low), while evidence was inadequate to determine the comparative accuracy of using angular versus linear measurement methods in postoperative dynamic radiographs for predicting pseudarthrosis (SOE: Insufficient).

One study (N=125) reported diagnostic accuracy of dynamic radiographs and computed tomography (CT) scans for identifying pseudarthrosis in patients who had undergone revision surgery for pseudarthrosis or adjacent segment pathology, using surgical exploration of fusion as the reference standard.¹⁶⁵ Medical records were retrospectively reviewed for patients operated on from January 2004 through December 2011. There were 262 levels evaluated (109 fused and 153 with pseudarthrosis). Most patients (84%) had revision surgery due to suspected pseudarthrosis, although it is unclear if patients were symptomatic. In dynamic radiographs magnified 150 percent, the optimal cutoff in interspinous motion to predict pseudarthrosis was 0.9 mm (AUC 0.899). Using cutoff criteria of interspinous motion ≥ 1 mm and superadjacent interspinous motion ≥ 4 mm resulted in similar values for diagnostic accuracy in dynamic radiographs versus a CT scan: sensitivity (86.3% vs. 87.2%), specificity (96.1% vs. 97.4%), positive predictive value (96.9% vs. 97.9%) and negative predictive value (83.4% vs. 84.4%) (SOE: Low).

3.13 Results, Key Question 12

One study (N=597, levels=1,203) assessed diagnostic accuracy of dynamic radiographs for predicting symptomatic pseudarthrosis in patients who were largely asymptomatic but required revision surgery.¹⁶⁴ Medical records from 2010 to 2019 were reviewed for eligible patients. The reference standard was intraoperative documentation of pseudarthrosis (36% of the patient sample); only 4.9 percent of patients required pseudarthrosis revision.¹⁶⁴ Pseudarthrosis rates increased as the number of operative levels increased from 22.2 percent with 1-level to 75 percent with 4-level surgery. In radiographs taken 1 year post-primary surgery, using an optimal cutoff of 1 mm interspinous motion (AUC 0.868) had high negative predictive value (99.6%) and sensitivity (89.7%); moderate specificity (81%); and low positive predictive value (13.7%) in identifying patients requiring revision surgery due to pseudarthrosis. Adding superadjacent interspinous motion ≥ 4 mm to 1 mm interspinous motion to the model, versus 1 mm alone,¹⁶⁵ reduced the number of patients and levels included in the authors' analysis but resulted in similar AUC. The positive predictive value was also decreased without improving the negative predictive value (SOE: Low).

One study rated high risk of bias (N=143 enrolled; 36 analyzed) validated an angular measurement method for predicting pseudarthrosis in patients with 10 months' minimum postoperative radiographic followup.¹⁶⁶ Medical records were retrospectively reviewed for eligible patients (years not reported); 1-year postoperative CTs (n=36) were used as the reference standard. Authors did not report whether patients were symptomatic or asymptomatic at the time of imaging. In dynamic radiographs at 150 percent magnification, the angle measurement method was calculated as the difference in angles between lines from specific landmarks in the spinous processes, while the standard linear method calculated differences in interspinous process distance between flexion and extension radiographs. Using 1 mm linear measurement cutoffs as reported in prior studies, suspected pseudarthrosis rates were lower using angular versus linear methods (N=143; 18.5% [45/242 levels] vs. 28% [68/242 levels], p=not reported).¹⁶⁶ In 1-year validation CTs (n=36; 66 levels), pseudarthrosis was identified in 13 patients (13 levels), of whom 5 underwent revision surgery; use of the angle method resulted in similar sensitivity (85%) but higher specificity (96%) versus the linear method (85% and 87%, respectively).¹⁶⁶ (SOE: Insufficient)

3.14 Results, Key Question 13

3.14 Key Question 13: In patients with cervical spondylotic myelopathy, what are the comparative effectiveness and harms of intraoperative neuromonitoring (e.g., with somatosensory or motor evoked potential measurements) versus no neuromonitoring on clinical outcomes in patients undergoing surgery?

3.14.1 Key Findings

- There was low-strength evidence of a similar likelihood of neurological complications with or without the use of intraoperative neuromonitoring (IONM) in ACDF for cervical myelopathy and radiculopathy (SOE: Low). This evidence only applies to patients undergoing ACDF and only one study reported the proportion of patients with myelopathy.

3.14.2 Description of Included Studies

Two retrospective NRSIs utilized large US claims databases (National Inpatient Sample [NIS]) of the Healthcare Cost and Utilization Project from 2009 to 2013 (N=141,007)¹⁶⁷ and PearlDiver from 2007 to 2014 (N=15,395)¹⁶⁸ to examine the effects of IONM versus no IONM in patients undergoing ACDF.

In the NIS study, 1:1 propensity score-matching, controlling for age, sex, indication, number of levels fused, Charlson Comorbidity Index (CCI) and admission type (elective, nonelective) was used (N=18,760).¹⁶⁷ There was no adjustment for confounders in the PearlDiver study.¹⁶⁸ The NIS data included inpatient data with no outpatient followup; the PearlDiver data included followup out to 30 days postoperatively. All data were collected from claims in the United States.

The mean age of participants was 54 years in the NIS study and reported by categories in the PearlDiver study (<45 years, 45-54, 55-64, 65-74, and >75; with the largest number of patients in the 45-54 age category). The average proportion of females was 51 and 52 percent, respectively. The NIS study enrolled a majority of White participants (80%), while the PearlDiver study did not report race/ethnicity (Appendix C).

Of patients with degenerative disease in the entire NIS, 42 percent of participants had radiculopathy alone and 31 percent had myelopathy (these proportions were not reported in the propensity score-matched NIS). Additionally, 66 percent of participants in the NIS study had a CCI of 0 (3.4% with a CCI of 3 or higher) and 84 percent had 1-2 level fusion, whereas the PearlDiver study did not report proportions with baseline radiculopathy, myelopathy, comorbidities, or levels fused.

The NIS study was rated moderate risk of bias due to study design.¹⁶⁷ The PearlDiver study was rated high risk of bias due to study design and lack of adjustment for potential confounders¹⁶⁸ (Appendix D). Concerns with these studies include the use of International Classification of Diseases codes to determine utilization, reliance on data from paid or adjusted claims rather than all claims, and changes in medical coverage policies.

3.14 Results, Key Question 13

3.14.3 Detailed Analysis

3.14.3.1 Outcomes

No studies reported fusion outcomes, pain, function, or quality of life.

3.14.3.2 Harms

There was low-strength evidence of a similar likelihood of neurological complications with or without the use of intraoperative neuromonitoring in ACDF (SOE: Low).

The NIS study included 18,760 patients who underwent ACDF in the propensity score-matched analyses from 2009 to 2013 and found no differences between IONM and no IONM in the rate of neurological complications (0.22% vs. 0.17%, $p=0.41$) or in the proportion of patients who required a hospital stay greater than 2 days (17.8% vs. 18.6%, $p=0.15$).¹⁶⁷

The PearlDiver database study included 15,395 patients who underwent ACDF from 2007 to 2014 for degenerative radiculopathy or myelopathy (IONM was used for 17.1% of patients, $N=2627$).¹⁶⁸ Although there was no propensity score matching or adjustments made for confounding variables, the results were similar to the NIS study. There was no difference in rate of neurologic complication within 30 days of the index procedure between IONM and no IONM (0.23% vs. 0.27%, $p=0.84$). However, younger patients were more likely to receive IONM (20.3% in patients less than 45 years of age compared to 13.6% in patients >75 years).

3.15 Results, Contextual Question 1

3.15 Contextual Question 1: What is the prevalence of cervical degenerative disease with spinal cord compression in asymptomatic patients?

Not all individuals with CDD that includes spinal cord compression experience pain, radiculopathy, myelopathy or other symptoms. A 2021 systematic review and meta-analysis rated moderate risk of bias included 11 studies (N=3,686) that reported cervical MRI results in healthy individuals.¹⁶⁹ In pooled analysis, the prevalence of asymptomatic spinal cord compression was 24.2 percent (range 5.3% to 59%; 95% CI 12.4% to 36%, $I^2=88$).

To help explain the high statistical heterogeneity in pooled analysis, studies of asymptomatic participants were stratified based on mean age (less than or equal to 60 years versus greater than 60 years). The prevalence of spinal cord compression was lower in the younger subgroup (7 studies, N=1841, prevalence 7.4%, 95% CI 2.8% to 12%, $I^2=40\%$) versus the older subgroup (4 studies, N=1845, prevalence 35.3%, 95% CI 14.1% to 56.5%, $I^2=94\%$). Studies were also stratified based on study location: America/Europe (6 studies, N=390, prevalence of spinal cord compression 39.7%, 95% CI 21.0% to 58.3%, $I^2=64\%$) versus Asia (5 studies, N=3296, prevalence of spinal cord compression 11.1%, 95% CI 1.6% to 20.5%, $I^2=83\%$). The study with the largest number of participants (N=1211) was conducted in Japan, enrolled younger participants (mean age 50 years) and reported the lowest prevalence of spinal cord compression (5.3%).¹⁷⁰ In this study, spinal cord compression was defined as when “the AP (anteroposterior) diameter of the spinal canal at its narrowest was less than or equal to the AP diameter of the spinal cord at the C5 vertebral level.”¹⁷⁰ This is in contrast to the study with the highest prevalence of participants with spinal cord compression (59%, N=183) that enrolled older participants (mean 66 years) and was conducted in the Czech Republic.¹⁷¹ The definition of spinal cord compression in this study was more liberal and was diagnosed when “a change in spinal cord contour at the level of an intervertebral disc on axial or sagittal MRI compared with that at the midpoint level of neighboring vertebrae.”¹⁷¹ In both studies, as expected, the prevalence of spinal cord compression increased with age.

3.16 Results, Contextual Question 2

3.16 Contextual Question 2: What is the natural history of untreated spinal cord compression in patients with cervical degenerative disease?

The natural history of degeneration of the cervical spine progressing to nonmyelopathic spinal cord compression (NMSCC) and ultimately CSM is a continuum of disease that remains poorly understood. Untreated spinal cord compression is most studied in the context of CSM. There is a subset of patients with spinal cord compression found on imaging who are asymptomatic. A recent systematic review by Nouri et al (2022)¹⁷² found the prevalence of asymptomatic spinal cord compression in healthy volunteers to be 24.2 percent (range 5.3% to 59%). A small series by Martin et al (2018)¹⁷³ looking at 20 asymptomatic patients with MRI evidence of spinal cord compression revealed that 2 (10%) developed symptoms of myelopathy at a median followup of 21 months. The largest prospective study evaluating the transition from NMSCC to CSM by Bednarik et al (2008) revealed that among 199 patients enrolled with NMSCC, 8 percent developed CSM at 1-year followup and 22.6 percent of patients developed CSM at median followup of 44 months (range 1-12 years).¹⁷⁴ Factors found to independently predict the development of myelopathy in a multivariate analysis included presence of radiculopathy, spinal cord cross-sectional area and compression ratio.¹⁷⁵

CSM is the leading cause of spinal cord dysfunction among adults worldwide.¹⁷⁶ The pathogenesis of CSM is due to both mechanical and neuropathic changes to the spinal cord and blood spinal cord barrier generated by compression on the spinal cord.¹⁷⁷⁻¹⁸⁰ The compressed cervical spinal cord is subjected to chronic hypoxic conditions due to dysfunction of endothelial cells as well as flattening and consequent loss of surrounding vessels.¹⁷⁸

While the natural history of CSM in patients varies greatly, it is generally thought of as a progressive disorder. This was confirmed in a recent systematic review¹⁸¹ that found moderate evidence from small prospective and retrospective studies that the proportion of patients who deteriorate by at least 1 point in the JOA scale ranged from 20 to 60 percent. It is important to point out that these studies did not consider the minimal detectable difference to define deterioration, which is >1 point based on reliability studies.^{182,183} The overall lack of large, well designed and controlled studies evaluating the natural history of untreated spinal cord compression in patients with CDDs impairs clinicians' ability to counsel patients. A recent clinical practice guideline provided by AO Spine suggested that either surgery or clinical observation are reasonable initial treatment options in mild CSM (e.g., mJOA score greater than or equal to 15).^{184,185}

Shimomura et al¹⁸⁶ evaluated prognostic factors for deterioration of patients with CSM treated nonoperatively. Their prospective study included 56 patients with mild CSM, 11 (20%) had clinical deterioration over a mean followup period of 35.6 months. Age, gender, followup period, developmental or dynamic canal factors (e.g., canal size of < 12mm) of cervical spine on plane lateral radiographs, presence of high intensity of the cord on T2 weighted MRI and circumferential spinal cord compression on axial MRI were all evaluated as possible predictors for progression of myelopathy. However, they found the only predictive factor was presence of circumferential spinal cord compression on axial MRI (adjusted OR 26.6, 95% CI 1.7 to 421.5).¹⁸⁶ More studies are needed to better define the natural history of untreated spinal cord compression in the setting of degenerative changes along with predictors of progression.

4. Discussion

4. Discussion

4.1 Findings in Relation to the Decisional Dilemmas

Cervical degenerative disease (CDD), which affects millions of older Americans, may lead to neck pain, radiculopathy, and myelopathy. Treatment of CDD, initially limited to conservative therapies (e.g., neck collar, traction, physiotherapy), has evolved to include instrumented and noninstrumented surgeries to decompress nerve roots and/or the spinal cord. Decisional dilemmas concerning best management of CDD include determination of whether one or more nonoperative treatments instead of surgery or in addition to surgery is preferred, and, if surgery is indicated, the determination of the most effective operative approaches and techniques for each individual patient. The key findings and strength of the evidence (SOE) are summarized in Table 9.

Fifty-seven randomized controlled trials (RCTs) (in 82 publications), 56 nonrandomized studies (in 57 publications), and 1 systematic review provided evidence for this review. The highest-quality evidence was for cervical arthroplasty versus anterior cervical discectomy and fusion (ACDF) in patients with cervical radiculopathy and/or myelopathy. Evidence for nonsurgical interventions was particularly limited. Similarly, there was no evidence to guide treatment for asymptomatic patients with radiographic spinal cord compression.

Conservative (nonoperative) therapy or operative treatment. There was insufficient evidence to determine the effectiveness of nonoperative compared with operative treatment for CDD, and limited evidence to suggest no important difference in pain beyond two weeks when a postoperative cervical collar was added to laminoplasty (SOE: Low). Post-operative pulsed electro-magnetic field stimulation in addition to ACDF was associated with a greater likelihood of fusion than ACDF alone (SOE: Low). Evidence for exercise therapy was insufficient.

Anterior or posterior surgery. Anterior approaches were primarily ACDF and included anterior cervical foraminotomy and anterior decompression without fusion; posterior approaches included posterior cervical discectomy and fusion, laminoplasty and posterior cervical foraminotomy. Single-level surgery was performed in patients with radiculopathy and two or more levels in patients with myelopathy. There was low strength of evidence of no difference between these approaches for improvement in pain, function, quality of life, or reoperation in patients with fewer than three operated levels (SOE: Low). There was limited evidence to suggest that a posterior approach is associated with increased likelihood of experiencing any serious adverse event in patients with greater than or equal to 3-level disease (SOE: Low). Selection bias, inadequate adjustment for potential confounding factors (e.g. age, comorbidities), confounding by indication, and other methodological limitations in nonrandomized studies of interventions (NRSIs) resulted in low or insufficient SOE for all outcomes, particularly in patients with ≥ 3 -level diseases.

Laminoplasty or laminectomy and fusion. In patients with cervical spondylotic myelopathy, there was moderate strength evidence indicating similar benefits on postoperative function between laminectomy and fusion compared with laminoplasty and no important difference in reoperation rates, although limited evidence suggests laminoplasty may be associated with fewer complications than laminectomy and fusion (SOE: Low).

Disc replacement or fusion. In patients with radiculopathy and/or myelopathy at one level, there was moderate strength evidence of no important difference between cervical arthroplasty and ACDF in pain or function. Cervical arthroplasty was associated with substantially decreased likelihood of reoperation (SOE: High) and slightly lower likelihood of any serious adverse event

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in the short term (SOE: Low), but there was no important difference between cervical arthroplasty and ACDF in serious adverse events longer term (SOE: Low). However, index level reoperation rates for ACDF may be influenced by removal an existing plate to treat adjacent segment disease. This may artificially inflate the reported reoperation rate for ACDF versus cervical arthroplasty. Studies did not consistently specify reasons for revision. Additionally, magnetic resonance imaging (MRI) artifact created by the artificial disc may obscure pathology while concerns related to fusion may be more apparent, leading to more revisions with ACDF vs. arthroplasty. The actual impact of these factors on reported reoperation rates is unclear.

Study findings were similar in patients with 2-level cervical arthroplasty or ACDF in pain and function and likelihood of reoperation at the index level, but the likelihood of an adverse event was slightly lower at 24 with months with cervical arthroplasty and no different at 120 months (SOE: Low). Evidence was sparse for this comparison beyond two levels. The majority of these cervical arthroplasty were industry funded and were frequently authored by individuals with industry-related conflicts of interest.

In patients with pseudarthrosis after ACDF, evidence on comparative effectiveness and harms of revision anterior arthrodesis versus a posterior approach was lacking.

ACDF graft choices. In patients undergoing ACDF, there was moderate strength evidence of no important difference between use of a standalone cage or a plate and cage in fusion rate, postoperative arm pain, function, quality of life, or subsidence. In a comparison of titanium/titanium-coated cages versus polyetheretherketone (PEEK) cages in ACDF, there was limited evidence to suggest that use of a PEEK cage results in a greater likelihood of fusion and function improvement than use of a titanium/titanium-coated cage (SOE: Low). In patients undergoing ACDF, there was also low strength evidence to suggest an increased risk of complications with the use of bone morphogenetic protein 2 (BMP-2) in the cervical spine compared with fusion without the use of BMP-2 (i.e., use of other osteogenic materials).

Other decisional dilemmas included the use of pre- and post-operative imaging findings and associations with better or worse outcomes, and the use or nonuse of intraoperative neuromonitoring on patients undergoing cervical spine surgery.

Role of imaging. Evidence for imaging to predict neurologic recovery was heterogeneous, as various study methods were used (e.g., different type and basis of classification of increased signal intensity, different outcomes, and different statistical analysis methods), thus making comparisons across studies challenging. In patients with cervical myelopathy, there was limited evidence to suggest that multisegmental T2-weighted increased signal intensity, sharp T2-weighted increased signal intensity, and increased signal intensity ratio are associated with poorer neurologic recovery (SOE: Low).

In an asymptomatic and symptomatic populations, there was limited evidence suggesting that postoperative ACDF dynamic radiographs can predict pseudarthrosis with surgical exploration used as the gold standard (SOE: Low).

Intraoperative neuromonitoring or no monitoring. There was limited evidence to suggest that patients undergoing anterior cervical discectomy and fusion with intraoperative neuromonitoring (IONM) had similar likelihood of neurological complications as patients undergoing surgery without IONM (SOE: Low). Two databases (National Inpatient Sample [NIS] and PearlDiver) were included, but only the NIS analysis used propensity score matching. The PearlDiver study did not match or control for confounders, but had similar results. In the total NIS sample, 42 percent of participants had radiculopathy alone and 31 percent had myelopathy (proportions not reported in the matched sample), 66 percent had a Charlson

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Comorbidity Index of 0, and 84 percent had 1-2 level fusion. The PearlDiver study did not report baseline radiculopathy, myelopathy, comorbidities or levels fused. These findings apply only to ACDF procedures; neither study evaluated posterior cervical procedures. Both studies relied on claims data to distinguish patients that had IONM versus those who did not, which may significantly underreport the number who received IONM.

Table 9. Summary of findings: cervical degenerative disease treatment

Key Question	Comparison	Fusion; Effect (SOE)	Pain; Effect (SOE)	Function; Effect (SOE)	Quality of Life; Effect (SOE)	Adverse Events; Effect (SOE)
KQ 1. Radiographic spinal cord compression, no myelopathy	Surgery vs. nonoperative treatment	No evidence	No evidence	No evidence	No evidence	No evidence
KQ 2. Radiographic spinal cord compression, mild to severe myelopathy	Surgery vs. nonoperative treatment	No evidence	No evidence	Insufficient	No evidence	Insufficient
KQ 3. CDD	Surgery vs. nonoperative treatment	No evidence	Insufficient	Insufficient	No evidence	No evidence
KQ 4. CDD	ACDF vs. ACDF + collar	Insufficient	Insufficient	Insufficient	No evidence	No evidence
	ACDF vs. ACDF + EMS	Small, favors ACDF + EMS (+)	Insufficient	Insufficient	No evidence	No evidence
	Laminoplasty vs. Laminoplasty + collar	NA	Similar (+)	Similar (+)	No evidence	No evidence
	Laminoplasty vs. laminoplasty + exercise	NA	Insufficient	No evidence	No evidence	No evidence
KQ 5. Cervical radiculopathy	Anterior vs. posterior surgery	Insufficient	<u>Neck and Arm pain:</u> Similar (+)	Similar (+)	Similar (+)	<u>Reoperation:</u> Similar (+)
KQ 6. CDD with ≥3 level disease	Anterior vs. posterior surgery	Insufficient	<u>Neck pain:</u> Similar (+) <u>Arm pain:</u> Insufficient	Similar (+)	Insufficient	<u>Mortality, severe dysphagia:</u> Similar (+) <u>Reoperation</u> Insufficient <u>SAE:</u> Moderate to Large, favors anterior (+)

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Key Question	Comparison	Fusion; Effect (SOE)	Pain; Effect (SOE)	Function; Effect (SOE)	Quality of Life; Effect (SOE)	Adverse Events; Effect (SOE)
KQ 7. Cervical myelopathy	Laminectomy and fusion vs. Laminoplasty	NA	Insufficient	Similar (++)	No evidence	<u>Reoperation:</u> Similar (++) <u>AEs:</u> Moderate to Large, favors laminoplasty (+)
KQ 8. CDD	Cervical arthroplasty vs. ACDF	NA	Similar (++)	Similar (++)	No evidence	<u>Reoperation:</u> Large, favors cervical arthroplasty: 1-level: (+++) 2-level: (+) <u>SAE:</u> Small, favors cervical arthroplasty (+) <u>Neurological events:</u> Similar 1-level: (+) 2-level: Insufficient
KQ9. ACDF	Standalone cage vs. plate and cage	Similar (++)	<u>Neck pain:</u> Similar (+) <u>Arm pain:</u> Insufficient	Similar (+)	Similar (+)	<u>Adjacent level ossification:</u> Similar (+)
	Titanium/titanium-coated vs. PEEK cage	Small, favoring PEEK (+)	Insufficient	Small, favoring PEEK (+)	No evidence	Insufficient
	Autograft vs. allograft vs. other osteogenic materials	Insufficient	Insufficient	Insufficient	Insufficient	<u>AEs:</u> Large, favors nonuse of BMP-2 (+)
KQ 10. Pseudarthrosis prior anterior fusion surgery	Posterior approach vs. revision anterior arthrodesis	No evidence	No evidence	No evidence	No evidence	No evidence
KQ 11. Myelopathy, prognostic utility of MRI	T2-weighted increased signal intensity and intensity ratio, sharp signal intensity	No evidence	No evidence	No evidence	No evidence	<u>Neurologic recovery:</u> favors no signal, less sharp signal, increased signal intensity ratio (+)

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Key Question	Comparison	Fusion; Effect (SOE)	Pain; Effect (SOE)	Function; Effect (SOE)	Quality of Life; Effect (SOE)	Adverse Events; Effect (SOE)
	Segmental abnormalities, diffusion tensor tactography, diffusion-based spectrum imaging, radionomic-based extra tree model	No evidence	No evidence	No evidence	No evidence	<u>Neurologic recovery:</u> Insufficient
KQ 12. Imaging to detect pseudarthrosis	Dynamic radiographs (asymptomatic)	Predicts pseudarthrosis (+)	NA	NA	NA	NA
	Dynamic radiographs (symptomatic)	Predicts pseudarthrosis (+)	NA	NA	NA	NA
	Angular measurement in dynamic radiographs (population NR)	Insufficient	NA	NA	NA	NA
KQ 13. CDD and ACDF	IONM vs. no IONM	NA	No evidence	No evidence	No evidence	<u>Neurologic complications:</u> Similar (+)

ACDF = anterior cervical discectomy and fusion; AE = adverse event; BMP-2 = bone morphogenetic protein 2; CDD = cervical degenerative disease; EMS = electromagnetic stimulation; IONM = intraoperative neuromonitoring; KQ = Key Question; MRI = magnetic resonance imaging; NA = not applicable; NR = not reported; PEEK = polyetheretherketone; SAE = serious adverse event; SOE = strength of evidence; T2 = T2 weighted image
Strength of Evidence: low (+), moderate (++), high (+++)

4.2 Implications for Clinical and Policy Decisions

This review was sponsored by the Congress of Neurological Surgeons (CNS) to update their 2009 guidelines on the management of CDD. Our review provides additional evidence that operative approaches to management of CDD generally result in improvement in pain, function, and quality of life postoperatively, as well as successful fusion (if a fusion surgery). In many cases patient-centered benefit outcomes between compared operative approaches and techniques were similar. The likelihood of general or specific adverse events, such as need for reoperation/revision surgery, were where most differences between therapies were observed and may help guide decision making regarding best operative approach for any given patient.

Our review provides additional support to the 2009 finding that preoperative MRI can help predict better or worse outcomes and to the 2009 recommendation discouraging use of BMP-2 in the cervical spine. Standalone cages for cervical fusion represent a newer design (Zero-P approved for use in the United States in 2008) and not covered in the 2009 guidelines. Although a more modern design, we did not find it superior to the use of anterior plating for most outcomes.

Gaps in the evidence make it difficult to create recommendations and inform policy. For example, challenges remain in determining the preferred course of action in patients with

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incidental findings of spinal cord compression on MRI. Although the natural history of non-myelopathic spinal cord compression is poorly understood, limited evidence suggests that some patients develop myelopathy over time, but it is not clear if any treatment provided prior to the development of symptoms results in better outcomes than treating symptomatic disease. Another challenge remaining is determining when conservative treatment may be preferred and what therapies are most effective compared with operative management or result in better outcomes when added to surgery. Good quality comparative evidence on conservative treatment was sparse in this review.

4.3 Strength and Limitations of the Systematic Review Process

Strengths. This review appears to provide the most comprehensive synthesis of evidence related to the comparative effectiveness of surgical treatment of CDD and identifies important gaps in the comparative evidence for many of them. Important strengths of this review include the use of a “best evidence” approach, where we focused our efforts on studies with least risk of bias, particularly RCTs when available and supplemented with nonrandomized studies that adjusted for potential prognostic variables where appropriate. We avoided use of nonrandomized studies that did not adjust for potential confounding (e.g., propensity score matching, statistical control for confounding variables) as the conclusion from such studies may differ from RCT evidence and are more likely to suffer from various important biases (see below). Another strength is our focus on outcomes of primary importance to patients including pain, function, and quality of life as improved patient outcomes may lead to higher quality patient care, as well as patient satisfaction with care. Additionally, interpretation of clinically important differences in mean change for continuous variables is challenging. A strength of our review is our categorization of the magnitude of effects for function and pain outcomes using the system described in our previous reviews to facilitate interpretation of results across trials and interventions by providing a level of consistency and objective benchmarks for comparison. We also added two Contextual Questions (on the natural history of untreated spinal cord compression and on the prevalence of CDD with spinal cord compression in asymptomatic patients) to provide context for this review.

Limitations. For many Key Questions, quantitative synthesis of evidence was not possible due to the poor quality of evidence available and lack of comparative evidence for some Key Questions. For some Key Questions evidence was limited to one study per comparison, making it difficult to draw conclusions about any specific treatment. While we did include NRSIs that made comparisons of interest, results from such studies should be interpreted cautiously. Limitations of these studies generally led to determination of insufficient evidence for many outcomes. Confounding by indication, lack of adequate control for confounding on important prognostic factors, as well as failure to adequately account for selection of patients and loss to followup in NRSIs were common methodologic concerns. For subjective patient-reported outcomes such as pain, NRSI results may be misleading due to the subjective nature of pain and the impact of nonspecific effects related to patient expectations regarding treatment and attention received. Analysis of data from large administrative claims-based databases present additional methodological challenges. Coding related to conditions, procedures and outcomes in such databases is focused on optimizing billing and there is a potential for misclassification of exposures and outcomes. Such databases are unable to account for some potential confounders or for factors that may impact decision-making regarding the appropriateness of a given procedure

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(e.g., use of an anterior versus posterior procedure). The large sample sizes available for administrative data may facilitate evaluation of rare outcomes and may demonstrate statistical significance when results may be of unclear clinical importance.

Other limitations of our review include the following:

1) Lack of RCT data for many comparisons and small sample sizes in most trials that precluded analyses on differential effectiveness and harms of interventions based on patient demographics, social determinants of health, severity of radiculopathy or myelopathy, number of vertebral levels involved, and other factors;

2) Poor reporting of adverse events in many studies and heterogeneity in what harms and adverse events were described;

3) Studies reporting vertebral levels affected (e.g., number of levels with pseudarthrosis, subsidence, needing reoperation) while not reporting the number of individuals experiencing a specific adverse event such as pseudarthrosis, thereby limiting the ability to use such studies in a pooled analysis in conjunction with studies reporting results in people rather than vertebral levels;

4) Heterogeneity in research design, interventions, and reported outcomes for several Key Questions that limit ability to draw conclusions on effectiveness across studies;

5) In most cases we were not able to assess for publication bias using graphical or statistical methods to evaluate any potential impact of small sample sizes due to insufficient number of studies per comparison; and

6) Limiting the evidence to English-language publications is a potential limitation, however we did not identify large numbers of non-English-language articles in our review of bibliographies.

4.4 Applicability

According to a NIS trend study of patients who underwent cervical fusion in 2013 for cervical spondylotic myelopathy (N=8181), the average patient was 60.6 years, slightly more likely to be male (54.3%), White (71.5%), with a CCI ≤ 2 (65.7%), have Medicare (44.6%) or private insurance (39.6%), and live in the South (43.8%).¹⁸⁷ In the absence of more recent data, this represents a “best guess” at defining the typical patient seen in clinical practice today. There were similarities and differences between the typical study participant in our review and the typical patient as described above.

Reasons for greater applicability of this body of evidence to clinical practice include: (1) many studies required enrolled study participants to have failed several weeks or months of conservative therapies, which is considered a valid approach to the management of mild degenerative cervical myelopathy (as is an operative approach);¹⁸⁴ (2) studies enrolled a balance of males and females; (3) most studies did not limit the upper age of enrollment and included individuals in their 60s or 70s (although the mean age of participants in most studies was in the 40s and 50s); and (4) studies often enrolled patients with a combination of radiculopathy and myelopathy, likely reflecting the condition of many US patients. Additionally, approximately 45 percent of studies included in this review were conducted in the United States.

Reasons for lower applicability to clinical practice include the exclusion of participants with a variety of common health conditions such as inflammatory arthritis, obesity, and diabetes. The risk of CDD increases with age and so do many other health conditions and comorbidities. For example, a large proportion of the US population is overweight or obese and an increasing proportion have diabetes. Excluding these populations from surgical intervention studies,

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because postoperative improvement may be reduced, decreases the applicability of study findings to many US patients needing operative management of their CDD. Additionally, few studies reported race or ethnicity. While those that did tended to enroll white participants, it is unclear how differences in access in populations of color may impact results.

4.5 Future Research

While it may not always be feasible to perform RCTs for surgical procedures, well-designed prospective comparative NRSIs with protocols using methods for patient selection and treatment allocation that mitigate possible selection bias and imbalances in prognostic factors and that follow protocols established *a priori* for comparable evaluation, measurement and treatment of groups would provide a valuable contribution to the evidence base. In order to evaluate the differential impact of patient characteristics and other factors, adequately powered RCTs are needed. Additionally, more explicit evaluation of procedure-specific (or device-specific) harms and adverse events is needed in future studies; ideally such studies would be powered to detect rare events. Future studies should also report the proportion of patients who experience a clinically important improvement in pain or function. This would provide valuable insight to complement data on average changes in continuous measures of pain, function, and quality of life for which there is difficulty describing clinically important effects. Studies should also estimate the minimally important between-group differences for included outcomes to facilitate interpretation of study findings.

4.6 Conclusions

There were generally similar benefits between surgical approaches, devices, and techniques compared in included studies for the treatment of CDD. However, there were some differences in the frequency of adverse events for some comparisons. Evidence indicates that the risk of reoperation is lower for artificial disc replacement than ACDF; however, indication for reoperation was not consistently described and the potential impact on re-operation at index level for plate removal to treat adjacent segment disease is unknown. Limited evidence also suggests a lower likelihood of experiencing any serious adverse event with ACDF than posterior cervical decompression and fusion and a lower risk for any complication with laminoplasty compared with laminectomy and fusion. There was limited evidence on the role of nonoperative management instead of surgery or in addition to surgery to treat CDD, and no evidence to determine benefits and harms of a revision anterior arthrodesis or posterior approach in patients with pseudarthrosis after prior anterior cervical fusion.

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Abbreviations and Acronyms

ACCF	anterior cervical corpectomy and fusion
ACDF	anterior cervical discectomy and fusion
ACD	anterior cervical decompression without fusion
ACF	anterior cervical foraminotomy
ADL	activities of daily living
AE	adverse event
AHRQ	Agency for Healthcare and Research Quality
ASD	adjacent segment disease
AUC	area under the curve
BMP-2	bone morphogenetic protein 2
CCI	Charlson Comorbidity Index
CDD	cervical degenerative disease
CI	confidence interval
CNS	Congress of Neurological Surgeons
COMI-neck	Core Outcome Measures Index-neck
CSM	cervical spondylotic myelopathy
CT	computed tomography
DRI	Disability Rating Index
DVT	deep vein thrombosis
EQ-5Dm	EuroQol-5 dimension instrument
EMS	electromagnetic stimulation
FDA	US Food and Drug Administration
HO	heterotopic ossification
HTE	Heterogeneity of treatment effect
IDE	Investigational Device Exemption
IONM	intraoperative neuromonitoring
ISI	increased signal intensity
JOA	Japanese Orthopaedic Association Scale
KQ	Key Question
MCS	mental component summary score
MD	mean difference
MDI	myelopathy disability index
mJOA	Modified Japanese Orthopaedic Association Scale
MRI	magnetic resonance imaging
NA	not applicable
NASS	North American Spine Society

NDI	Neck Disability Index
NIS	National Inpatient Sample
NMSCC	nonmyelopathic spinal cord compression
NR	not reported
N(P)RS	numeric (pain) rating scale
NRSI	nonrandomized studies of interventions
OPLL	ossification of the posterior longitudinal ligament
OR	odds ratio
PCDF	posterior cervical decompression and fusion
PCF	posterior cervical foraminotomy
PCS	physical component summary score
PEEK	polyetheretherketone
PEG	percutaneous endoscopic gastrostomy
PEMF	pulsed electro-magnetic field
PICOTS	Population, Intervention, Comparator, Outcome, Time, Setting
PL	profile likelihood
PROMIS-29	patient-reported outcome measurement information system
QOL	quality of life
RCT	randomized controlled trial
RR	risk ratio
SAE	serious adverse event
SF-12	12-Item Short Form Health Survey
SF-36	36-Item Short Form Health Survey
SIR	signal intensity ratio
SOE	strength of evidence
SSED	Summary of Safety and Effectiveness Data (FDA)
T2	T2 weighted image
VAS	visual analogue scale
WHO Grade	World Health Organization Grade scale

Appendix A. Methods

A1.1 Search Strategy

The searches were conducted by Key Question, with the exception of EMBASE.

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>

Search Strategy for KQ1-2:

- 1 Spinal Cord Compression/
- 2 "spinal cord compression".ti,ab.
- 3 exp Cervical Vertebrae/
- 4 3 and degenerat*.ti,ab.
- 5 (cervical and degenerat*).ti,ab.
- 6 (1 or 2) and (4 or 5)
- 7 su.fs.
- 8 (surgery or surgical).ti,ab.
- 9 6 and (7 or 8)
- 10 limit 9 to (comparative study or controlled clinical trial or meta analysis or randomized controlled trial or "systematic review")
- 11 (random* or control* or NRSI or observational or prospective or retrospective or review or systematic or "meta analysis" or "metaanalysis").ti,ab,pt.
- 12 9 and 11
- 13 10 or 12
- 14 (Animals/ or Models, Animal/ or Disease Models, Animal/) not Humans/
- 15 ((animal or animals or avian or bird or birds or bovine or canine or cow* or dog or dogs or cat or cats or feline or hamster* or horse* or lamb or lamb* or mouse or mice or monkey or monkeys or murine or pig or piglet* or pigs or porcine or primate* or rabbit* or rat or rats or rodent* or songbird* or veterinar*) not (human* or patient*)).ti,kf,jw.
- 16 or/14-15
- 17 13 not 16
- 18 limit 17 to yr="1980 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>

Search Strategy for KQ3-4:

- 1 exp Cervical Vertebrae/su [Surgery]
- 2 1 and degenerat*.ti,ab.
- 3 (cervical and degenerat*).ti,ab.
- 4 su.fs.
- 5 (surgery or surgical).ti,ab.
- 6 3 and (4 or 5)
- 7 2 or 6
- 8 limit 7 to (comparative study or controlled clinical trial or meta analysis or randomized controlled trial or "systematic review")
- 9 (random* or control* or NRSI or observational or prospective or retrospective or review or systematic or "meta analysis" or "metaanalysis").ti,ab,pt.

10 7 and 9
11 8 or 10
12 (Animals/ or Models, Animal/ or Disease Models, Animal/) not Humans/
13 ((animal or animals or avian or bird or birds or bovine or canine or cow* or dog or dogs or cat or cats or feline or hamster* or horse* or lamb or lamb* or mouse or mice or monkey or monkeys or murine or pig or piglet* or pigs or porcine or primate* or rabbit* or rat or rats or rodent* or songbird* or veterinar*) not (human* or patient*)).ti,kf,jw.
14 or/12-13
15 11 not 14
16 limit 15 to yr="1980 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>
Search Strategy for KQ5:

1 Radiculopathy/su [Surgery]
2 radiculopathy.ti,ab.
3 su.fs.
4 (surgery or surgical).ti,ab.
5 2 and (3 or 4)
6 1 or 5
7 (anterior and posterior).ti,ab.
8 6 and 7
9 limit 8 to (comparative study or controlled clinical trial or meta analysis or randomized controlled trial or "systematic review")
10 (random* or control* or NRSI or observational or prospective or retrospective or review or systematic or "meta analysis" or "metaanalysis").ti,ab,pt.
11 8 and 10
12 9 or 11
13 (Animals/ or Models, Animal/ or Disease Models, Animal/) not Humans/
14 ((animal or animals or avian or bird or birds or bovine or canine or cow* or dog or dogs or cat or cats or feline or hamster* or horse* or lamb or lamb* or mouse or mice or monkey or monkeys or murine or pig or piglet* or pigs or porcine or primate* or rabbit* or rat or rats or rodent* or songbird* or veterinar*) not (human* or patient*)).ti,kf,jw.
15 or/13-14
16 12 not 15
17 limit 16 to yr="2006 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>
Search Strategy for KQ6:

1 exp Cervical Vertebrae/su [Surgery]
2 1 and degenerat*.ti,ab.
3 (cervical and degenerat*).ti,ab.
4 su.fs.
5 (surgery or surgical).ti,ab.
6 3 and (4 or 5)

7 2 or 6
8 (anterior and posterior).ti,ab.
9 7 and 8
10 limit 9 to (comparative study or controlled clinical trial or meta analysis or randomized controlled trial or "systematic review")
11 (random* or control* or NRSI or observational or prospective or retrospective or review or systematic or "meta analysis" or "metaanalysis").ti,ab,pt.
12 9 and 11
13 10 or 12
14 (Animals/ or Models, Animal/ or Disease Models, Animal/) not Humans/
15 ((animal or animals or avian or bird or birds or bovine or canine or cow* or dog or dogs or cat or cats or feline or hamster* or horse* or lamb or lamb* or mouse or mice or monkey or monkeys or murine or pig or piglet* or pigs or porcine or primate* or rabbit* or rat or rats or rodent* or songbird* or veterinar*) not (human* or patient*)).ti,kf,jw.
16 or/14-15
17 13 not 16
18 limit 17 to yr="2006 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>
Search Strategy for KQ7:

1 Spinal Cord Diseases/
2 (spondylo* or cervical or myelopathy).ti.
3 1 and 2
4 ((spondylo* or cervical) and myelopathy).ti,ab.
5 3 or 4
6 Laminectomy/ or Laminoplasty/
7 (laminectomy or laminoplasty).ti,ab.
8 6 or 7
9 5 and 8
10 limit 9 to (comparative study or controlled clinical trial or meta analysis or randomized controlled trial or "systematic review")
11 (random* or control* or NRSI or observational or prospective or retrospective or review or systematic or "meta analysis" or "metaanalysis").ti,ab,pt.
12 9 and 11
13 10 or 12
14 (Animals/ or Models, Animal/ or Disease Models, Animal/) not Humans/
15 ((animal or animals or avian or bird or birds or bovine or canine or cow* or dog or dogs or cat or cats or feline or hamster* or horse* or lamb or lamb* or mouse or mice or monkey or monkeys or murine or pig or piglet* or pigs or porcine or primate* or rabbit* or rat or rats or rodent* or songbird* or veterinar*) not (human* or patient*)).ti,kf,jw.
16 or/14-15
17 13 not 16
18 limit 17 to yr="2006 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>

Search Strategy for KQ8:

1 Spinal Cord Diseases/
2 1 and myelopathy.ti.
3 Radiculopathy/
4 (spondylo* or cervical).ti.
5 (2 or 3) and 4
6 ((spondylo* or cervical) and (radiculopathy or myelopathy)).ti,ab.
7 5 or 6
8 Arthroplasty/ and Discectomy/
9 (arthroplasty and (discectomy or discectomy)).ti,ab.
10 8 or 9
11 7 and 10
12 limit 11 to (comparative study or controlled clinical trial or meta analysis or randomized controlled trial or "systematic review")
13 (random* or control* or NRSI or observational or prospective or retrospective or review or systematic or "meta analysis" or "metaanalysis").ti,ab,pt.
14 11 and 13
15 12 or 14
16 (Animals/ or Models, Animal/ or Disease Models, Animal/) not Humans/
17 ((animal or animals or avian or bird or birds or bovine or canine or cow* or dog or dogs or cat or cats or feline or hamster* or horse* or lamb or lamb* or mouse or mice or monkey or monkeys or murine or pig or piglet* or pigs or porcine or primate* or rabbit* or rat or rats or rodent* or songbird* or veterinar*) not (human* or patient*)).ti,kf,jw.
18 or/16-17
19 15 not 18
20 limit 19 to yr="2006 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>

Search Strategy for KQ9:

1 Discectomy/
2 (discectomy or discectomy).ti,ab.
3 (1 or 2) and cervical.ti,ab.
4 3 and anterior.ti,ab.
5 (interbody or graft* or type or device* or "standalone" or "stand alone" or traditional or plat* or cage*).ti,ab.
6 4 and 5
7 limit 6 to (comparative study or controlled clinical trial or meta analysis or randomized controlled trial or "systematic review")
8 (random* or control* or NRSI or observational or prospective or retrospective or review or systematic or "meta analysis" or "metaanalysis").ti,ab,pt.
9 6 and 8
10 7 or 9
11 (Animals/ or Models, Animal/ or Disease Models, Animal/) not Humans/

12 ((animal or animals or avian or bird or birds or bovine or canine or cow* or dog or dogs or cat or cats or feline or hamster* or horse* or lamb or lamb* or mouse or mice or monkey or monkeys or murine or pig or piglet* or pigs or porcine or primate* or rabbit* or rat or rats or rodent* or songbird* or veterinar*) not (human* or patient*)).ti,kf,jw.

13 or/11-12

14 10 not 13

15 limit 14 to yr="2006 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>

Search Strategy for KQ10:

1 Pseudarthrosis/

2 pseudarthrosis.ti,ab.

3 1 or 2

4 cervical.ti,ab.

5 3 and 4

6 Arthrodesis/

7 arthrodesis.ti,ab.

8 6 or 7

9 (anterior or posterior).ti,ab.

10 5 and (8 or 9)

11 limit 10 to (comparative study or controlled clinical trial or meta analysis or randomized controlled trial or "systematic review")

12 (random* or control* or NRSI or observational or prospective or retrospective or review or systematic or "meta analysis" or "metaanalysis").ti,ab,pt.

13 10 and 12

14 11 or 13

15 (Animals/ or Models, Animal/ or Disease Models, Animal/) not Humans/

16 ((animal or animals or avian or bird or birds or bovine or canine or cow* or dog or dogs or cat or cats or feline or hamster* or horse* or lamb or lamb* or mouse or mice or monkey or monkeys or murine or pig or piglet* or pigs or porcine or primate* or rabbit* or rat or rats or rodent* or songbird* or veterinar*) not (human* or patient*)).ti,kf,jw.

17 15 or 16

18 14 not 17

19 limit 18 to yr="2006 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>

Search Strategy for KQ11:

1 Spinal Cord Diseases/dg [Diagnostic Imaging]

2 1 and myelopathy.ti,ab.

3 ((cervical or spondylo*) and myelopathy).ti,ab.

4 2 or 3

5 Magnetic Resonance Imaging/

6 ("magnetic resonance imag*" or "mri").ti,ab.

7 ("pre operative" or "preoperative").ti,ab.

8 (5 or 6) and 7
9 limit 8 to "prognosis (maximizes sensitivity)"
10 4 and 9
11 limit 10 to yr="1980 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>
Search Strategy for KQ12:

1 Pseudarthrosis/dg [Diagnostic Imaging]
2 pseudarthrosis.ti,ab.
3 Diagnostic Imaging/
4 dg.fs.
5 (image or imaging).ti,ab.
6 2 and (or/3-5)
7 1 or 6
8 exp "Sensitivity and Specificity"/
9 (sensitivity or specificity or accuracy or predict* or "reference standard" or "gold standard").ti,ab.
10 "reproducibility of results"/
11 8 or 9 or 10
12 7 and 11
13 limit 12 to yr="1980 -Current"

Database: Ovid MEDLINE(R) ALL <1946 to February 15, 2023>
Search Strategy for KQ13:

1 Spinal Cord Diseases/
2 1 and myelopathy.ti,ab.
3 ((cervical or spondylo*) and myelopathy).ti,ab.
4 2 or 3
5 exp Monitoring, Intraoperative/
6 (intraoperat* and monitor*).ti,ab.
7 (neuromonitor* or somatosensory or "motor evoked potential").ti,ab.
8 7 and intraoperat*.ti,ab.
9 5 or 6 or 8
10 4 and 9
11 limit 10 to yr="2006 -Current"

Database: EMBASE
Search Strategy:

('cervical degenerative disc disease'/exp OR 'cervical degenerative disease'/exp OR 'cervical degenerative':ab,ti OR (('cervicobrachial neuralgia'/exp OR 'cervicobrachial neuralgia') AND degenerative) OR (myelopathy AND degenerative) OR (pseudarthrosis AND cervical AND fusion AND (anterior OR posterior))) AND ('diagnostic imaging' OR 'nuclear magnetic resonance imaging' OR 'neuromonitoring') AND ('prognosis' OR 'predictive value' OR 'predictive

validity' OR 'sensitivity and specificity') AND [embase]/lim NOT ([embase]/lim AND [medline]/lim)

Database: EBM Reviews - Cochrane Database of Systematic Reviews <2005 to February 2023>
Search Strategy:

- 1 (spine or spinal or radiculopathy or myelopathy).ti.
- 2 (cervical and degenerat*).ti,ab.
- 3 1 or 2
- 4 limit 3 to full systematic reviews

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ1-2:

- 1 Spinal Cord Compression/
- 2 "spinal cord compression".ti,ab.
- 3 exp Cervical Vertebrae/
- 4 3 and degenerat*.ti,ab.
- 5 (cervical and degenerat*).ti,ab.
- 6 (1 or 2) and (4 or 5)
- 7 su.fs.
- 8 (surgery or surgical).ti,ab.
- 9 6 and (7 or 8)
- 10 limit 9 to yr="1980 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ3-4:

- 1 Cervical Vertebrae/ (1027)
- 2 1 and degenerat*.ti,ab.
- 3 (cervical and degenerat*).ti,ab.
- 4 su.fs.
- 5 (surgery or surgical).ti,ab.
- 6 (2 or 3) and (4 or 5)
- 7 limit 6 to yr="1980 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ5:

- 1 Radiculopathy/
- 2 radiculopathy.ti,ab.
- 3 su.fs.
- 4 (surgery or surgical).ti,ab.
- 5 (1 or 2) and (3 or 4)
- 6 (anterior and posterior).ti,ab.
- 7 5 and 6

8 limit 7 to yr="2006 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ6:

-
- 1 Cervical Vertebrae/
 - 2 1 and degenerat*.ti,ab.
 - 3 (cervical and degenerat*).ti,ab.
 - 4 su.fs.
 - 5 (surgery or surgical).ti,ab.
 - 6 (2 or 3) and (4 or 5)
 - 7 (anterior and posterior).ti,ab.
 - 8 6 and 7
 - 9 limit 8 to yr="2006 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ7:

-
- 1 Spinal Cord Diseases/
 - 2 (spondylo* or cervical or myelopathy).ti.
 - 3 1 and 2
 - 4 ((spondylo* or cervical) and myelopathy).ti,ab.
 - 5 3 or 4
 - 6 Laminectomy/ or Laminoplasty/
 - 7 (laminectomy or laminoplasty).ti,ab.
 - 8 5 and (6 or 7)
 - 9 limit 8 to yr="2006 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ8:

-
- 1 Spinal Cord Diseases/
 - 2 1 and myelopathy.ti.
 - 3 Radiculopathy/
 - 4 (spondylo* or cervical).ti.
 - 5 (2 or 3) and 4
 - 6 ((spondylo* or cervical) and (radiculopathy or myelopathy)).ti,ab.
 - 7 5 or 6
 - 8 Arthroplasty/ and Discectomy/
 - 9 (arthroplasty and (discectomy or discectomy)).ti,ab.
 - 10 8 or 9
 - 11 7 and 10
 - 12 limit 11 to yr="2006 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ9:

1 Discectomy/
2 (discectomy or diskectomy).ti,ab.
3 (1 or 2) and cervical.ti,ab.
4 3 and anterior.ti,ab.
5 (interbody or graft* or type or device* or "standalone" or "stand alone" or traditional or plat* or cage*).ti,ab.
6 4 and 5
7 limit 6 to yr="2006 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ10:

1 Pseudarthrosis/
2 pseudarthrosis.ti,ab.
3 1 or 2
4 cervical.ti,ab.
5 3 and 4
6 Arthrodesis/
7 arthrodesis.ti,ab.
8 6 or 7
9 (anterior or posterior).ti,ab.
10 5 and (8 or 9)
11 limit 10 to yr="2006 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ11:

1 Spinal Cord Diseases/
2 1 and myelopathy.ti,ab.
3 ((cervical or spondylo*) and myelopathy).ti,ab.
4 2 or 3
5 Magnetic Resonance Imaging/
6 ("magnetic resonance imag*" or "mri").ti,ab.
7 ("pre operative" or "preoperative").ti,ab.
8 (5 or 6) and 7
9 4 and 8
10 limit 9 to yr="1980 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ12:

1 Pseudarthrosis/
2 pseudarthrosis.ti,ab.
3 Diagnostic Imaging/
4 dg.fs.

5 (image or imaging).ti,ab.
6 (1 or 2) and (or/3-5)
7 exp "Sensitivity and Specificity"/
8 (sensitivity or specificity or accuracy or predict* or "reference standard" or "gold standard").ti,ab.
9 "reproducibility of results"/
10 7 or 8 or 9
11 6 and 10

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <February 2023>
Search Strategy for KQ13:

1 Spinal Cord Diseases/
2 1 and myelopathy.ti,ab.
3 ((cervical or spondylo*) and myelopathy).ti,ab.
4 2 or 3
5 exp Monitoring, Intraoperative/
6 (intraoperat* and monitor*).ti,ab.
7 (neuromonitor* or somatosensory or "motor evoked potential").ti,ab.
8 7 and intraoperat*.ti,ab.
9 5 or 6 or 8
10 4 and 9

A2.1 Expanded Methods

2.1.1 Literature Search Strategy

We conducted electronic searches in Ovid MEDLINE®, EMBASE, and Cochrane CENTRAL from 1980 to February 15, 2023 (see **Appendix A1.1** for full strategies). For Key Questions that compare operative approaches, we searched databases for studies published after 2006 (studies published in 2007 or earlier were included in the 2009 guidelines).¹ Additionally, we reviewed all studies included in the 2009 guidelines for inclusion in this review.¹ For Key Questions not covered by the 2009 guidelines (e.g., operative versus nonoperative studies, neuromonitoring studies) we searched the databases from 1980 to the present in order to identify relevant, earlier studies based on when technologies such as neuromonitoring and advanced imaging were first used in research trials. Reference lists of included systematic reviews were screened for additional studies and relevant references were carried forward. A Federal Register notification for a Supplemental Evidence and Data for Systematic review (SEADS) portal was posted from August 12th to September 12th, 2022, for submission of unpublished studies.

2.1.1.1 PICOTS

Criteria were established *a priori* to determine eligibility for inclusion and exclusion of abstracts in accordance with the Agency for Healthcare Research and Quality (AHRQ) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* (hereafter the “AHRQ Methods Guide”).² Study eligibility criteria for this CER were based on the population, intervention, comparisons, outcomes, timing, settings, and study designs of interest (PICOTS) framework and the Key Questions. The population of interest was adults (aged ≥18 years) with symptomatic

cervical degenerative disease (e.g., pain, radiculopathy, myelopathy) for all Key Questions except for Key Question 1, which included asymptomatic patients. We also captured effectiveness and harms of surgery based on patient characteristics, disease characteristics and radiographic characteristics, where available. Details regarding the PICOTS are summarized in **Table A-1**. Specific outcomes for each management approach considered are described in detail in **Table A-1**.

For this review, management included cervical spine surgery, non-surgical treatments, intraoperative monitoring, imaging to identify symptomatic pseudarthrosis (vertebrae do not fuse successfully) after cervical fusion surgery, and preoperative MRI to predict neurological recovery in myelopathy. Comparisons included any eligible intervention, placebo, waitlist, or active control.

Study designs considered for inclusion were comparative studies of any design including trials of any size and observational studies ($N \geq 50$). For Key Questions 11-12 and studies focused on harms as the primary outcome, we considered large intervention series ($N \geq 50$) eligible, including those with single arms where everyone received the same intervention. We reviewed existing systematic reviews and included their results if appropriate. References lists of systematic reviews were also used to identify relevant studies. Descriptive studies with no outcome data or studies that included only data from one point in time (cross-sectional) were not included. For Key Questions 1-10, pre-post single-arm studies and systematic reviews published prior to 2007 were excluded, as these studies would have been captured in the guidelines. Also excluded were commentaries, letters, and narrative reviews, as were studies published only as conference abstracts. Inclusion was restricted to English-language articles, and studies of nonhuman subjects were excluded (**Appendix B**).

To ensure accuracy, all excluded abstracts were dual reviewed by two investigators. Each full-text article was independently reviewed for eligibility by two team members. All disagreements were resolved through a consensus process between investigators.

Contextual Questions were addressed without presepecified inclusion criteria; we used studies identified in our main searches to answer the Contextual Questions.

Table A-1. PICOTS – inclusion and exclusion criteria

PICOT	Include	Exclude
Population	<ul style="list-style-type: none"> Age 18 and above with symptomatic cervical degenerative disease (e.g., pain, radiculopathy, myelopathy) for all KQs except for KQ1, which includes asymptomatic patients Effectiveness and harms of surgery based on patient characteristics, disease characteristics and radiographic characteristics (e.g., age, gender, comorbidities [e.g., comorbid lumbar disease, autoimmune disease, neurological disease, mental illness, Down’s syndrome], severity of cervical degenerative disease, Frailty Index, sagittal vertical aspect, degree of kyphosis, prior treatment [e.g., bracing, traction, medications, massage, acupuncture, injections, chiropractic care, spinal manipulation], duration of pain, skill of surgeon) 	<ul style="list-style-type: none"> Younger than 18 years Patients without cervical degenerative disease Nonhumans

PICOT	Include	Exclude
Interventions	<ul style="list-style-type: none"> • Cervical spine surgery (e.g., discectomy, disc replacement, fusion up to T2, arthroplasty, laminectomy, laminoplasty, corpectomy, cervical hybrid surgery, foraminotomy, ACDF cage vs. ACDF cage + plate) • Non-surgical treatments (e.g., heat, exercise, acupuncture, drugs, radiofrequency ablation, steroid injections, Botox® for neck pain, psychological strategies [e.g., cognitive behavioral therapy], occupational therapy, multidisciplinary rehabilitation) • Intraoperative neuromonitoring • Imaging to identify symptomatic pseudarthrosis after cervical fusion surgery • Preoperative MRI to predict neurologic recovery in myelopathy 	<ul style="list-style-type: none"> • Preoperative imaging using CT or plain films • KQ4: intraoperative therapy • KQ7: laminectomy without fusion
Comparators	<ul style="list-style-type: none"> • Any included intervention • Placebo, waitlist, active control • No comparator (KQs 11 and 12) 	<ul style="list-style-type: none"> • Nonoperative intervention versus nonoperative intervention without surgical comparator
Outcomes	<ul style="list-style-type: none"> • Pain, sensory function, motor function, gait, quality of life (e.g., VAS, NRS, NDI, SF-36, SF-12, EQ-5Dm, mJOA score, Nurick score, MDI, PROMIS-29), dysphagia scales, return to work • Fusion rate, reoperation rate • Harms (e.g., withdrawals due to adverse events, serious adverse events, new symptomatic adjacent segment disease, postoperative infection, device failure, ossification of the posterior ligament, development of kyphotic deformity) • Sensitivity and specificity of imaging after cervical fusion surgery 	<ul style="list-style-type: none"> • Nonvalidated instruments
Timing	<ul style="list-style-type: none"> • All time periods 	None
Setting	<ul style="list-style-type: none"> • Inpatient, outpatient, ambulatory surgical centers 	None
Study types and designs	<ul style="list-style-type: none"> • RCTs, prospective trials and retrospective observational studies with a control group (study N≥50), current systematic reviews • KQs 11-13 and studies focused on harms as a primary outcome: large intervention series (N≥50; can be single arm, but everyone received the same intervention) 	<ul style="list-style-type: none"> • KQ1-10: pre-post single-arm studies, case series (everyone selected based on outcome), case reports, systematic reviews published prior to 2007 • KQ11-13: pre-post non-intervention studies, case series, case reports, systematic reviews published prior to 2007
Language	<ul style="list-style-type: none"> • English language 	<ul style="list-style-type: none"> • Non-English

Abbreviations: ACDF = anterior cervical discectomy and fusion; CT = computed tomography; EQ-5D = EuroQol-5 dimension instrument; KQ = Key Question; MDI = myelopathy disability index; MRI = magnetic resonance imaging; mJOA = modified Japanese orthopedic association scale; NDI = neck disability index; NRS = numerical pain rating scale; PROMIS-29 = patient reported outcome measurement information system; RCT = randomized controlled trial; QOL = quality of life; SF = short form health survey (12 or 36 items); VAS = visual analogue scale

2.1.2 Data Abstraction and Data Management

Dual review of abstracts was conducted using prespecified inclusion criteria and DistillerSR software version 2.35 (<https://www.distillersr.com/>). Discrepancies were resolved by discussion and consensus. Investigators tracked results in EndNote version 20.1 (Thomson Reuters, New York, NY). For studies meeting inclusion criteria, evidence tables were constructed with the following data: study design, author, year, setting, country, sample size, patient characteristics (e.g., age, gender, obesity, number of vertebral levels involved, severity of radiculopathy and/or myelopathy), effectiveness-related outcomes (e.g., validated pain, function and quality of life measures), as well as treatment-related adverse effects/harms) and results relevant to each Key Question as outlined in the previous PICOTS section (**Appendix C**).

2.1.3 Risk of Bias Assessment of Individual Studies

Predefined criteria were used to assess the risk of bias (also referred to as quality or internal validity) for each individual included study, using criteria appropriate for the study design (**Table A-2** and **Appendix D1.1**). Controlled trials and observational studies were assessed using a priori established criteria consistent with the AHRQ-Evidence-based Practice Center (EPC) approach recommended in the chapter, “Assessing the Risk of Bias of Individual Studies,” described in the AHRQ Methods Guide.² RCTs were evaluated using criteria and methods developed by the Cochrane Back and Neck Group,³ nonrandomized studies of interventions (NRSI) and other observational studies of interventions were evaluated using criteria developed by the U.S. Preventive Services Task Force,⁴ and followed the approach recommended in the AHRQ Methods Guide chapter “Assessing the Risk of Bias of Individual Studies When Comparing Medical Interventions.”² For randomized controlled trials (RCTs), we focused on randomization, allocation concealment, analysis according to randomized groups (intent-to-treat analysis), and attrition. NRSIs that controlled for potential prognostic variables were included to fill gaps in evidence when RCTs did not sufficient address the Key Questions.

Each study was independently reviewed for risk of bias by two team members. Any disagreements were resolved through consensus. Based on the risk of bias assessment, included studies were rated as having “low,” “moderate,” or “high” risk of bias (**Appendix D2.1**). Studies rated high risk of bias were not excluded a priori, but were considered to be less reliable than low or moderate risk of bias studies when synthesizing the evidence.

Table A-2. Criteria for grading the risk of bias of individual studies

Rating	Description and Criteria
Low	Least risk of bias, results generally considered valid Employ valid methods for selection, inclusion, and allocation of patients to treatment; report similar baseline characteristics in different treatment groups; clearly describe attrition and have low attrition; use appropriate means for preventing bias (e.g., blinding of patients, care providers, and outcomes assessors); and use appropriate analytic methods (e.g., intention-to-treat analysis)
Moderate	Susceptible to some bias but not enough to necessarily invalidate results May not meet all criteria for low risk of bias, but no flaw is likely to cause major bias; the study may be missing information making it difficult to assess limitations and potential problems Category is broad; studies with this rating will vary in strengths and weaknesses; some studies rated moderate risk of bias are likely to be valid, while others may be only possibly valid

Rating	Description and Criteria
High	<p>Significant flaws that imply biases of various kinds that may invalidate results; “fatal flaws” in design, analysis or reporting; large amounts of missing information; discrepancies in reporting; or serious problems with intervention delivery</p> <p>Studies are at least as likely to reflect flaws in the study design or execution as the true difference between the compared interventions</p> <p>Considered to be less reliable than studies rated moderate or low risk of bias when synthesizing the evidence, particularly if discrepancies between studies are present</p>

Table A-2 is taken from the Cervical Degenerative Disease Protocol, published online at <https://effectivehealthcare.ahrq.gov/sites/default/files/product/pdf/cervical-degenerative-protocol.pdf>

Because most studies were rated moderate risk of bias, we called out in the text studies rated high risk of bias as extra caution should be exercised when drawing conclusions from such studies.

2.1.4 Data Analysis and Synthesis

Evidence tables identify study characteristics, results of interest, and risk of bias ratings for all included studies and summary tables highlight the main findings. Studies were reviewed and highlighted using a hierarchy-of-evidence approach, where the best evidence is the focus of the synthesis for each Key Question. Since the Key Questions varied in nature and scope, the approach to synthesis also varied. We analyzed the evidence according to Key Question, using both qualitative (narrative) and where possible quantitative (meta-analysis) methods. RCTs were prioritized and studies with lower risk of bias ratings were given more weight in our synthesis for each clinical indication and outcome.

Meta-analyses were conducted to obtain more precise effect estimates for comparative effectiveness of various interventions for cervical spine. To determine the appropriateness of meta-analysis, we considered clinical and methodological diversity and assessed statistical heterogeneity. We conducted meta-analyses of randomized and nonrandomized evidence separately. For binary outcomes (e.g., overall success, neurological success, re-operation, fusion), risk ratio (RR) was used as the effect measure. For continuous outcomes (e.g. NDI, neck or arm pain, Japanese Orthopaedic Association Scale [JOA] scores, quality of life), mean difference (MD) was used as the effect measure as the studies reported outcomes using the same scale, or the outcomes could be converted to the same scale (e.g. pain, converted to 0-100 scale) (**Table A-3**). Adjusted mean differences between interventions were used if reported; otherwise, MD was calculated using the follow-up score if reported and then the change score from the baseline. When the reported measure of dispersion for each intervention group was not specified as standard deviation (SD) or standard error (SE), judgement was made based on the reported p-values for comparing the intervention groups and the magnitude of dispersion measures of similar studies. When SD was not reported, or could not be calculated from the reported data, it was imputed using the average coefficient of variation from the other included studies reporting the same outcome.

Table A-3. Definition of effect sizes

Effect Size	Definition
Small effect	MD 0.5 to 1.0 points on a 0 to 10-point scale, 5 to 10 points on a 0 to 100-point scale SMD 0.2 to 0.5 RR/OR 1.2 to 1.4
Moderate effect	MD >1 to 2 points on a 0 to 10-point scale, >10 to 20 points on a 0 to 100-point scale SMD >0.5 to 0.8 RR/OR 1.5 to 1.9
Large effect	MD >2 points on a 0 to 10-point scale, >20 points on a 0 to 100-point scale SMD >0.8 RR/OR ≥2.0

MD = mean difference; OR = odds ratio; RR = relative risk; SMD = standardized mean difference

Table A-3 taken from the Cervical Degenerative Disease Protocol, published online at

<https://effectivehealthcare.ahrq.gov/sites/default/files/product/pdf/cervical-degenerative-protocol.pdf>

A random effects model based on the profile likelihood method⁵ was used to obtain pooled RR and MD. When applicable, the primary analyses were stratified by the length of follow up: short term (≤ 6 months), intermediate term (6 to 60 months), long term (> 60 months), or using the actual follow up time. For arm pain success and arm pain score, when studies reported data from each arm separately, we conducted an optimistic analysis by using data from the arm with larger effect size, and a conservative analysis by data from the arm with smaller effect size. For arm pain score, we also conducted a sensitivity analysis using the average pain score of both arms. Additional sensitivity analyses were conducted by excluding studies rated high risk of bias.

Statistical heterogeneity among the studies was assessed using Cochran’s χ^2 test and the I^2 statistic.⁶ For analyses with at least 10 trials, we constructed funnel plots and performed the Egger test to detect small sample effects (a marker for potential publication bias).⁷ All meta-analyses were conducted using Stata/SE 16.1 (StataCorp, College Station, TX).

To help determine the degree of effect, we examined the magnitude of relative risks and mean differences according to **Table A-3**. There were instances where a statistically significant difference between treatments was of such a small magnitude as to not be clinically meaningful. Conversely, there were instances where a small, moderate, or large effect was found but was not statistically significant.

2.1.5 Grading the Strength of the Body of Evidence

The EPC strength of evidence (SOE) rating for each body of evidence was assessed as high, moderate, low, or insufficient, using the approach described in the AHRQ Methods Guide,² based on study limitations, consistency, directness, precision, and reporting bias. These criteria were applied regardless of whether evidence was synthesized quantitatively or qualitatively. The I^2 statistic was used to help assess consistency in pooled analyses; The confidence intervals surrounding effect estimates were reviewed for clear benefit, no effect, and clear harms to aid in assessing precision. We considered evidence from both randomized trials and nonrandomized studies in determining strength of evidence with greater weight given to randomized studies. Strength of evidence ratings reflected our confidence or certainty in the findings (**Appendix G1.1**). Strength of evidence was considered insufficient when evidence was sparse, of poor quality or too conflicting such that we were unable to draw conclusions. SOE was initially assessed by one researcher and confirmed by a second. Descriptions of criteria and overall grades are described in **Table A-4** and **Appendix G**.

Table A-4. Strength of evidence grades and definitions

Grade	Definition
High	We are very confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has few or no deficiencies. We believe that the findings are stable, i.e., another study would not change the conclusions.
Moderate	We are moderately confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	We have limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Insufficient	We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

Table A-4 taken from page 18 of the AHRQ Methods Guide.²

2.1.6 Peer Review and Public Commentary

An associate editor from a different EPC reviewed the draft report. Experts were invited to provide external peer review of this systematic review; AHRQ also provided comments. In addition, the draft report was posted on the AHRQ website June 9 to July 7, 2023, for public comment. All comments were reviewed and used to inform revisions to the draft report.

Appendix B. Included Studies

1. Abbott A, Halvorsen M, Dederig A. Is there a need for cervical collar usage post anterior cervical decompression and fusion using interbody cages? A randomized controlled pilot trial. *Physiotherapy Theory & Practice*. 2013;29(4):290-300. doi: 10.3109/09593985.2012.731627. PMID: 23074995
2. Aggarwal RA, Srivastava SK, Bhosale SK, et al. Prediction of surgical outcome in compressive cervical myelopathy: a novel clinicoradiological prognostic score. *Journal of Craniovertebral Junction & Spine*. 2016;7(2):82-6. doi: 10.4103/0974-8237.181828. PMID: 27217653.
3. Ajiboye RM, D'Oro A, Ashana AO, et al. Routine use of intraoperative neuromonitoring during ACDFs for the treatment of spondylotic myelopathy and radiculopathy is questionable: a review of 15,395 cases. *Spine*. 2017;42(1):14-9. doi: 10.1097/BRS.0000000000001662. PMID: 27120059.
4. Alvin MD, Lubelski D, Abdullah KG, et al. Cost-utility analysis of anterior cervical discectomy and fusion with plating (ACDFP) versus posterior cervical foraminotomy (PCF) for patients with single-level cervical radiculopathy at 1-year follow-up. *Clinical Spine Surgery : A Spine Publication*. 2016;29(2):E67-72. doi: 10.1097/BSD.0000000000000099. PMID: 26889994.
5. Alvin MD, Lubelski D, Abdullah KG, et al. Cost-utility analysis of anterior cervical discectomy and fusion with plating (ACDFP) versus posterior cervical foraminotomy (PCF) for patients with single-level cervical radiculopathy at 1-year follow-up. *Clinical Spine Surgery : A Spine Publication*. 2016;29(2):E67-72. doi: 10.1097/BSD.0000000000000099. PMID: 26889994.
6. Anderson PA, Sasso RC, Riew KD. Comparison of adverse events between the Bryan artificial cervical disc and anterior cervical arthrodesis. *Spine*. 2008;33(12):1305-12. doi: 10.1097/BRS.0b013e31817329a1. PMID: 18496341.
7. Arnold PM, Anderson KK, Selim A, et al. Heterotopic ossification following single-level anterior cervical discectomy and fusion: results from the prospective, multicenter, historically controlled trial comparing allograft to an optimized dose of rhBMP-2. *Journal of Neurosurgery Spine*. 2016;25(3):292-302. doi: 10.3171/2016.1.SPINE15798. PMID: 27129045.
8. Arnold PM, Anderson KK, Selim A, et al. Heterotopic ossification following single-level anterior cervical discectomy and fusion: results from the prospective, multicenter, historically controlled trial comparing allograft to an optimized dose of rhBMP-2. *Journal of Neurosurgery Spine*. 2016;25(3):292-302. doi: 10.3171/2016.1.SPINE15798. PMID: 27129045.
9. Arnold PM, Sasso RC, Janssen ME, et al. i-Factor TM bone graft vs autograft in anterior cervical discectomy and fusion: 2-year follow-up of the randomized single-blinded food and drug administration investigational device exemption study. *Neurosurgery*; 2018. p. 377-84.
10. Arnold PM, Sasso RC, Janssen ME, et al. Efficacy of i-Factor bone graft versus autograft in anterior cervical discectomy and fusion: results of the prospective, randomized, single-blinded food and drug administration investigational device exemption study. *Spine*. 2016;41(13):1075-83. doi: 10.1097/BRS.0000000000001466. PMID: 26825787.

11. Arnold PM, Vaccaro AR, Sasso RC, et al. Six-year follow-up of a randomized controlled trial of i-FACTOR peptide-enhanced bone graft versus local autograft in single-level anterior cervical discectomy and fusion. *Neurosurgery*. 2022 Apr 1;92(4):725-33. doi: 10.1227/neu.0000000000002290. PMID: 36700705.
12. Asher AL, Devin CJ, Kerezoudis P, et al. Comparison of outcomes following anterior vs posterior fusion surgery for patients with degenerative cervical myelopathy: an analysis from quality outcomes database. *Neurosurgery*. 2019;84(4):919-26. doi: 10.1093/neuros/nyy144. PMID: 29741718.
13. Badhiwala JH, Ellenbogen Y, Khan O, et al. Comparison of the inpatient complications and health care costs of anterior versus posterior cervical decompression and fusion in patients with multilevel degenerative cervical myelopathy: a retrospective propensity score-matched analysis. *World Neurosurgery*. 2020;134:e112-e9. doi: 10.1016/j.wneu.2019.09.132. PMID: 31574327.
14. Badhiwala JH, Nassiri F, Witiw CD, et al. Investigating the utility of intraoperative neurophysiological monitoring for anterior cervical discectomy and fusion: analysis of over 140,000 cases from the National (Nationwide) Inpatient Sample data set. *Journal of Neurosurgery Spine*. 2019;31(1):76-86. doi: 10.3171/2019.1.SPINE181110. PMID: 30925481.
15. Baker JD, Harada GK, Tao Y, et al. The impact of modic changes on preoperative symptoms and clinical outcomes in anterior cervical discectomy and fusion patients. *Neurospine*. 2020;17(1):190-203. doi: 10.14245/ns.2040062.031. PMID: 32252168.
16. Balouch E, Burapachaisri A, Woo D, et al. Assessing postoperative pseudarthrosis in Anterior Cervical Discectomy and Fusion (ACDF) on dynamic radiographs using novel angular measurements. *Spine (Phila Pa 1976)*. 2022 Aug 15;47(16):1151-6. doi: 10.1097/BRS.0000000000004375. PMID: 35853174.
17. Baskin DS, Ryan P, Sonntag V, et al. A prospective, randomized, controlled cervical fusion study using recombinant human bone morphogenetic protein-2 with the CORNERSTONE-SR allograft ring and the ATLANTIS anterior cervical plate. *Spine*. 2003;28(12):1219-24; discussion 25. doi: 10.1097/01.BRS.0000065486.22141.CA. PMID: 12811263.
18. Bhashyam N, De la Garza Ramos R, Nakhla J, et al. Thirty-day readmission and reoperation rates after single-level anterior cervical discectomy and fusion versus those after cervical disc replacement. *Neurosurg Focus*. 2017;42(2):E6. doi: 10.3171/2016.11.Focus16407. PMID: 28142261.
19. Blizzard DJ, Caputo AM, Sheets CZ, et al. Laminoplasty versus laminectomy with fusion for the treatment of spondylotic cervical myelopathy: short-term follow-up. *European Spine Journal*. 2017;26(1):85-93. doi: 10.1007/s00586-016-4746-3. PMID: 27554354.
20. Broekema AEH, Simoes de Souza NF, Soer R, et al. Noninferiority of posterior cervical foraminotomy vs anterior cervical discectomy with fusion for procedural success and reduction in arm pain among patients with cervical radiculopathy at 1 year: the FACET randomized clinical trial. *JAMA Neurol*. 2023 Jan 1;80(1):40-8. doi: 10.1001/jamaneurol.2022.4208. PMID: 36409485.
21. Burkus JK, Haid RW, Traynelis VC, et al. Long-term clinical and radiographic outcomes of cervical disc replacement with the Prestige disc: results from a prospective randomized controlled clinical trial. *Journal of Neurosurgery Spine*. 2010;13(3):308-18. doi: 10.3171/2010.3.SPINE09513. PMID: 20809722.

22. Burkus JK, Traynelis VC, Haid RW, Jr., et al. Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial: Clinical article. *Journal of Neurosurgery Spine*. 2014;21(4):516-28. doi: 10.3171/2014.6.SPINE13996. PMID: 25036218.
23. Chen X, Shi L, Yu X, et al. Comparative study of artificial cervical disc replacement and anterior cervical discectomy/fusion in the treatment of cervical spondylotic myelopathy. *International journal of clinical and experimental medicine*. 2019;12(8):10597-604p.
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Appendix C. Evidence Tables

Please see the Excel file, located at <https://effectivehealthcare.ahrq.gov/products/cervical-degenerative-disease/research>.

Appendix D. Risk of Bias Assessment

D1.1 Risk of Bias Assessment Methods

Based on the risk of bias assessment, included studies were rated as having “low,” “moderate,” or “high” risk of bias. Studies rated high risk of bias were not excluded a priori, but were considered to be less reliable than low or moderate risk of bias studies when synthesizing the evidence.

Table D-1. Criteria for grading the risk of bias of individual studies

Rating	Description and Criteria
Low	Least risk of bias, results generally considered valid Employ valid methods for selection, inclusion, and allocation of patients to treatment; report similar baseline characteristics in different treatment groups; clearly describe attrition and have low attrition; use appropriate means for preventing bias (e.g., blinding of patients, care providers, and outcomes assessors); and use appropriate analytic methods (e.g., intention-to-treat analysis)
Moderate	Susceptible to some bias but not enough to necessarily invalidate results May not meet all criteria for low risk of bias, but no flaw is likely to cause major bias; the study may be missing information making it difficult to assess limitations and potential problems Category is broad; studies with this rating will vary in strengths and weaknesses; some studies rated moderate risk of bias are likely to be valid, while others may be only possibly valid
High	Significant flaws that imply biases of various kinds that may invalidate results; “fatal flaws” in design, analysis or reporting; large amounts of missing information; discrepancies in reporting; or serious problems with intervention delivery Studies are at least as likely to reflect flaws in the study design or execution as the true difference between the compared interventions Considered to be less reliable than studies rated moderate or low risk of bias when synthesizing the evidence, particularly if discrepancies between studies are present

Table 2 is taken from the Cervical Degenerative Disease Protocol, published online at <https://effectivehealthcare.ahrq.gov/sites/default/files/product/pdf/cervical-degenerative-protocol.pdf>

D2.1 Risk of Bias Tables

Please see the Excel file for Risk of Bias assessments, located at <https://effectivehealthcare.ahrq.gov/products/cervical-degenerative-disease/research>.

Appendix E. List of Excluded Studies

Exclusion codes: E1 = Ineligible population; E2 = Ineligible or no intervention; E3 = Ineligible or no comparison; E4 = Ineligible or no outcome; E5 = Ineligible study design; E6 = Ineligible publication type; E7 = Ineligible sample size; E8 = Systematic review, secondary analysis, or meta-analysis used as a source document only to identify individual studies; E9 = Article or systematic review covered by a more recent systematic review; E10 = Foreign Language; E11 = Cohort study, no confounding adjustment; E12 = Key Question with sufficient RCT evidence, observational study not needed

1. Aarabi B, Koltz M, Ibrahim D. Hyperextension cervical spine injuries and traumatic central cord syndrome. *Neurosurg*. 2008;25(5):E9. doi: 10.3171/FOC.2008.25.11.E9. PMID: 18980483. Exclusion: E1.
2. Abbas S, Spurgas M, Szewczyk B, et al. A comparison of minimally invasive posterior cervical decompression and open anterior cervical decompression and instrumented fusion in the surgical management of degenerative cervical myelopathy. *Neurosurg Focus*. 2016 Jun;40(6):E7. doi: 10.3171/2016.3.FOCUS1650. PMID: 27246490. Exclusion: E11.
3. Abd-Alrahman N, Dokmak AS, Abou-Madawi A. Anterior cervical discectomy (ACD) versus anterior cervical fusion (ACF), clinical and radiological outcome study. *Acta Neurochir (Wien)*. 1999;141(10):1089-92. doi: 10.1007/s007010050487. PMID: 10550654. Exclusion: E3.
4. Abudouaini H, Wu T, Liu H, et al. Comparison of the postoperative motion stabilization between anterior cervical decompression and fusion with a zero-profile implant system and a plate-cage construct. *World Neurosurg*. 2022 Oct;166:e484-e94. doi: 10.1016/j.wneu.2022.07.033. PMID: 35843577. Exclusion: E11.
5. Adamson TE. Microendoscopic posterior cervical laminoforaminotomy for unilateral radiculopathy: results of a new technique in 100 cases. *J Neurosurg*. 2001 Jul;95(1 Suppl):51-7. doi: 10.3171/spi.2001.95.1.0051. PMID: 11453432. Exclusion: E5.
6. Ahmed AF, Al Dosari MAA, Al Kuwari A, et al. The outcomes of stand alone polyetheretherketone cages in anterior cervical discectomy and fusion. *Int Orthop*. 2021 01;45(1):173-80. doi: 10.1007/s00264-020-04760-1. PMID: 32803359. Exclusion: E6.
7. Ahmed OEF, Galal A. Single level anterior cervical discectomy and fusion versus dynamic cervical implant: clinical and radiological outcome. *Egyptian Journal of Neurology, Psychiatry and Neurosurgery*. 2020;56(1) doi: 10.1186/s41983-020-0153-0. Exclusion: E7.
8. Ahn JS, Lee JK, Kim JH. Comparative study of clinical outcomes of anterior cervical discectomy and fusion using autobodyne graft or cage with bone substitute. *Asian spine j*. 2011 Sep;5(3):169-75. doi: 10.4184/asj.2011.5.3.169. PMID: 21892389. Exclusion: E11.
9. Ahn PG, Kim KN, Moon SW, et al. Changes in cervical range of motion and sagittal alignment in early and late phases after total disc replacement: radiographic follow-up exceeding 2 years. *J Neurosurg Spine*. 2009 Dec;11(6):688-95. doi: 10.3171/2009.7.SPINE0946. PMID: 19951021. Exclusion: E7.
10. Ahn SS, Paik HK, Chin DK, et al. The fate of adjacent segments after anterior cervical discectomy and fusion: The influence of an anterior plate system. *World Neurosurg*. 2016 May;89:42-50. doi: 10.1016/j.wneu.2016.01.013. PMID: 26828457. Exclusion: E11.

11. Ahn SS, So WS, Ku MG, et al. Radiologic findings and risk factors of adjacent segment degeneration after anterior cervical discectomy and fusion : a retrospective matched cohort study with 3-year follow-up using MRI. *J. 2016 Mar*;59(2):129-36. doi: 10.3340/jkns.2016.59.2.129. PMID: 26962418. Exclusion: E3.
12. Ahn Y. The current state of cervical endoscopic spine surgery: an updated literature review and technical considerations. *Expert Rev Med Devices. 2020 Dec*;17(12):1285-92. doi: 10.1080/17434440.2020.1853523. PMID: 33210554. Exclusion: E8.
13. Ahsan MK, Awwal MA, Khan SI, et al. Open-door laminoplasty for multilevel cervical spondylotic myelopathy and ossification of the posterior longitudinal ligament (OPLL) using titanium reconstruction miniplate and screws. *Mymensingh Med J. 2017 07*;26(3):558-68. PMID: 28919610. Exclusion: E7.
14. Ajiboye RM, Zoller SD, Ashana AA, et al. Regression of disc-osteophyte complexes following laminoplasty versus laminectomy with fusion for cervical spondylotic myelopathy. *Int J Spine Surg. 2017 ISASS (E-mail: info@ISASS;11(3):129-37p. doi: 10.14444/4017. Exclusion: E4.*
15. Akbari KK, Badikillaya V, Venkatesan M, et al. Do intraoperative neurophysiological changes during decompressive surgery for cervical myeloradiculopathy affect functional outcome? A prospective study. *Global spine j. 2022 Apr*;12(3):366-72. doi: 10.1177/2192568220951779. PMID: 32959684. Exclusion: E7.
16. Al Barbarawi MM, Audat ZA, Obeidat MM, et al. Decompressive cervical laminectomy and lateral mass screw-rod arthrodesis. Surgical analysis and outcome. *Scoliosis. 2011 May 19*;6:10. doi: 10.1186/1748-7161-6-10. PMID: 21595968. Exclusion: E3.
17. Al Eissa S, Konbaz F, Aldeghaither S, et al. Anterior cervical discectomy and fusion complications and thirty-day mortality and morbidity. *Cureus. 2020 Apr 12*;12(4):e7643. doi: 10.7759/cureus.7643. PMID: 32411545. Exclusion: E5.
18. Alafifi T, Kern R, Fehlings M. Clinical and MRI predictors of outcome after surgical intervention for cervical spondylotic myelopathy. *J Neuroimaging. 2007 Oct*;17(4):315-22. doi: 10.1111/j.1552-6569.2007.00119.x. PMID: 17894620. Exclusion: E11.
19. Albert TJ. CORR Insights(R): reoperation after cervical disc arthroplasty versus anterior cervical discectomy and fusion: a meta-analysis. *Clin Orthop. 2016 May*;474(5):1317-8. doi: 10.1007/s11999-016-4753-z. PMID: 26906011. Exclusion: E6.
20. Albert TJ, Coric D, Kim HJ, et al. Clinical obesity in total disc replacement and anterior cervical discectomy and fusion patients through five years follow-up. *Spine. 2015*:146-9. Exclusion: E1.
21. Albert TJ, Pinto M, Smith MD, et al. Accuracy of SPECT scanning in diagnosing pseudoarthrosis: a prospective study. *J Spinal Disord. 1998 Jun*;11(3):197-9. PMID: 9657542. Exclusion: E7.
22. Alhashash M, Boehm H, Shousha M. Management of symptomatic cervical spine pseudarthrosis: a suggested algorithm for surgical planning. *Int J Spine Surg. 2021 Dec*;15(6):1167-73. doi: 10.14444/8148. PMID: 35086874. Exclusion: E11.
23. Alimi M, Njoku I, Hofstetter CP, et al. Anterior Cervical Discectomy and Fusion (ACDF): comparison between zero profile implants and anterior cervical plate and spacer. *Cureus. 2016 Apr 17*;8(4):e573. doi: 10.7759/cureus.573. PMID: 27200226. Exclusion: E5.
24. Alluri RK, Vaishnav AS, Fourman MS, et al. Anterior cervical discectomy and fusion versus cervical disc replacement in patients with significant cervical spondylosis. *Clin Spine Surg. 2022 03 01*;35(2):E327-E32. doi: 10.1097/BSD.0000000000001250. PMID: 35213422. Exclusion: E12.
25. Almeida ND, Lee R, Wei C, et al. Coagulation profile as a significant risk factor for short-term complications and mortality after anterior cervical discectomy and fusion. *World Neurosurg. 2021 04*;148:e74-e86. doi: 10.1016/j.wneu.2020.12.007. PMID: 33307267. Exclusion: E5.

26. Alomar SA, Maghrabi Y, Baeesa SS, et al. Outcome of anterior and posterior endoscopic procedures for cervical radiculopathy due to degenerative disk disease: a systematic review and meta-analysis. *Global spine j.* 2021;12(7):1546-60. doi: 10.1177/21925682211037270. PMID: 34402323. Exclusion: E5.
27. Alomari S, Liu A, Westbroek E, et al. Effect of patient's sex on early perioperative outcomes following anterior cervical discectomy and fusion. *J Clin Neurosci.* 2021 Nov;93:247-52. doi: 10.1016/j.jocn.2021.09.015. PMID: 34656256. Exclusion: E3.
28. Alonso F, Rustagi T, Schmidt C, et al. Failure patterns in standalone anterior cervical discectomy and fusion implants. *World Neurosurg.* 2017 Dec;108:676-82. doi: 10.1016/j.wneu.2017.09.071. PMID: 28942019. Exclusion: E5.
29. Alosch H, Riley LH, 3rd, Skolasky RL. Insurance status, geography, race, and ethnicity as predictors of anterior cervical spine surgery rates and in-hospital mortality: an examination of United States trends from 1992 to 2005. *Spine.* 2009 Aug 15;34(18):1956-62. doi: 10.1097/BRS.0b013e3181ab930e. PMID: 19652634. Exclusion: E6.
30. Ament JD, Karnati T, Kulubya E, et al. Treatment of cervical radiculopathy: a review of the evolution and economics. *Surg Neurol Int.* 2018;9:35. doi: 10.4103/sni.sni_441_17. PMID: 29527393. Exclusion: E8.
31. Ament JD, Yang Z, Chen Y, et al. A novel quality-of-life utility index in patients with multilevel cervical degenerative disc disease: comparison of anterior cervical discectomy and fusion with total disc replacement. *Spine.* 2015 Jul 15;40(14):1072-8. doi: 10.1097/BRS.0000000000000898. PMID: 25811263. Exclusion: E4.
32. Ament JD, Yang Z, Nunley PD, et al. Cost utility analysis of the cervical artificial disc vs. fusion for the treatment of two-level symptomatic degenerative disc disease: five-year follow-up. *Spine.* 2015:110-2. Exclusion: E6.
33. An HS, Al-Shihabi L, Kurd M. Surgical treatment for ossification of the posterior longitudinal ligament in the cervical spine. *J Am Acad Orthop Surg.* 2014 Jul;22(7):420-9. doi: 10.5435/JAAOS-22-07-420. PMID: 24966248. Exclusion: E6.
34. An HS, Simpson JM, Glover JM, et al. Comparison between allograft plus demineralized bone matrix versus autograft in anterior cervical fusion. A prospective multicenter study. *Spine (Phila Pa 1976).* 1995 Oct 15;20(20):2211-6. PMID: 8545714. Exclusion: E7.
35. Anakwenze OA, Auerbach JD, Milby AH, et al. Sagittal cervical alignment after cervical disc arthroplasty and anterior cervical discectomy and fusion: results of a prospective, randomized, controlled trial. *Spine.* 2009 Sep 01;34(19):2001-7. doi: 10.1097/BRS.0b013e3181b03fe6. PMID: 19730207. Exclusion: E4.
36. Anderson PA, Matz PG, Groff MW, et al. Laminectomy and fusion for the treatment of cervical degenerative myelopathy. *J Neurosurg Spine.* 2009 Aug;11(2):150-6. doi: 10.3171/2009.2.SPINE08727. PMID: 19769494. Exclusion: E6 - background.
37. Anderson PA, Nassr A, Currier BL, et al. Evaluation of adverse events in total disc replacement: a meta-analysis of FDA summary of safety and effectiveness data. *Global spine j.* 2017 Apr;7(1 Suppl):76S-83S. doi: 10.1177/2192568216688195. PMID: 28451497. Exclusion: E8.
38. Anderson PA, Puschak TJ, Sasso RC. Comparison of short-term SF-36 results between total joint arthroplasty and cervical spine decompression and fusion or arthroplasty. *Spine.* 2009 Jan 15;34(2):176-83. doi: 10.1097/BRS.0b013e3181913cba. PMID: 19139668. Exclusion: E3.
39. Anderson PA, Sasso RC, Rouleau JP, et al. The Bryan Cervical Disc: wear properties and early clinical results. *Spine J.* 2004 Nov-Dec;4(6 Suppl):303S-9S. doi: 10.1016/j.spinee.2004.07.026. PMID: 15541681. Exclusion: E3.

40. Anderson-Smits C, Sing D, Dmitriev A, et al. A comparative analysis of secondary surgeries of six total cervical disc arthroplasty devices to cervical arthrodesis at 5-years. *Pharmacoepidemiology and drug safety*. 2016;25(64):2016-08. doi: 10.1002/pds.4070. Exclusion: E6.
41. Ando M, Tamaki T, Matsumoto T, et al. Can postoperative deltoid weakness after cervical laminoplasty be prevented by using intraoperative neurophysiological monitoring? *J Clin Monit Comput*. 2019 Feb;33(1):123-32. doi: 10.1007/s10877-018-0141-4. PMID: 29667095. Exclusion: E2.
42. Angevine PD. Comment: a prospective, randomized trial comparing expansile cervical laminoplasty and cervical laminectomy and fusion for multilevel cervical myelopathy. *Clin Neurosurg*. 2012 United States Oxford University Press (E-mail: agents@lww;70(2):277p. doi: 10.1227/NEU.0b013e3182305669. Exclusion: E6.
43. Anonymous. Corrigendum to: "Surgery for Degenerative Cervical Myelopathy: a Nationwide Registry-Based Observational Study With Patient-Reported Outcomes" by Sasha Gulati, MD, PhD, Vette Vangen-Lonne, MS, Oystein P Nygaard, MD, PhD, Agnete M Gulati, MD, PhD, Tommy A Hammer, MD, Tonje O Johansen, MD, Wilco C Peul, MD, PhD, Oyvind O Salvesen, MSc, PhD, Tore K Solberg, MD, PhD. *Neurosurgery*, nyab259, <https://doi.org/10.1093/neuros/nyab259>. *Neurosurgery*. 2021 Oct 13;89(5):943. doi: 10.1093/neuros/nyab334. PMID: 34432876. Exclusion: E5.
44. Aragonés M, Hevia E, Barrios C. Polyurethane on titanium unconstrained disc arthroplasty versus anterior discectomy and fusion for the treatment of cervical disc disease: a review of level I-II randomized clinical trials including clinical outcomes. *Eur Spine J*. 2015 Dec;24(12):2735-45. doi: 10.1007/s00586-015-4228-z. PMID: 26363559. Exclusion: E8.
45. Arnasson O, Carlsson CA, Pellettieri L. Surgical and conservative treatment of cervical spondylotic radiculopathy and myelopathy. *Acta Neurochir (Wien)*. 1987;84(1-2):48-53. doi: 10.1007/bf01456351. PMID: 3030063. Exclusion: E11.
46. Arnold PM, Anderson KK, Foley KT. Heterotopic ossification following single-level anterior cervical discectomy and fusion: results from a prospective, multicenter, historically-controlled trial comparing allograft to an optimized dose of rhBMP-2. *Spine journal*. 2015 Netherlands Elsevier Inc;Conference: 30th annual meeting of the north american spine society, NASS. Vol.15(10 Supplement 1):180Sp. doi: 10.1016/j.spinee.2015.07.224. Exclusion: E6.
47. Arnold PM, Kopjar B, Tetreault L, et al. Tobacco smoking and outcomes of surgical decompression in patients with symptomatic degenerative cervical spondylotic myelopathy. *Clinical neurosurgery*. Conference. 2016;63(165) doi: 10.1227/01.neu.0000489731.76982.a4. Exclusion: E6.
48. Arnold PM, Sasso R, Janssen M, et al. Efficacy of i-Factor™ bone graft versus autograft in ACDF: prospective randomized FDA IDE study results. *J Neurosurg*. 2016 to 2016-05-04;124(4):A1209-p. doi: 10.3171/2016.4.JNS.AANS2016abstracts. Exclusion: E6 - conference abstract.
49. Arnold PM, Sasso RC, Janssen ME, et al. I-factor™ bone graft versus autograft in anterior cervical discectomy and fusion: two-year follow-up of the randomized single-blinded food and drug administration investigational device exemption study. *Spine journal*. 2016 to 2016-10-29;16(10):S153-S4p. doi: 10.1016/j.spinee.2016.07.051. Exclusion: E6.
50. Arnold PM, Sasso RC, Janssen ME, et al. I-Factor™ bone graft vs. autograft in anterior cervical discectomy and fusion: two-year follow-up of the randomized single-blinded food and drug administration investigational device exemption study. *Spine*. 2016(366):2016-12. Exclusion: E6.

51. Arts MP, Wolfs JF, Corbin TP. The CASCADE trial: effectiveness of ceramic versus PEEK cages for anterior cervical discectomy with interbody fusion; protocol of a blinded randomized controlled trial. *BMC Musculoskelet Disord*. 2013 Aug 16;14:244. doi: 10.1186/1471-2474-14-244. PMID: 23947902. Exclusion: E6.
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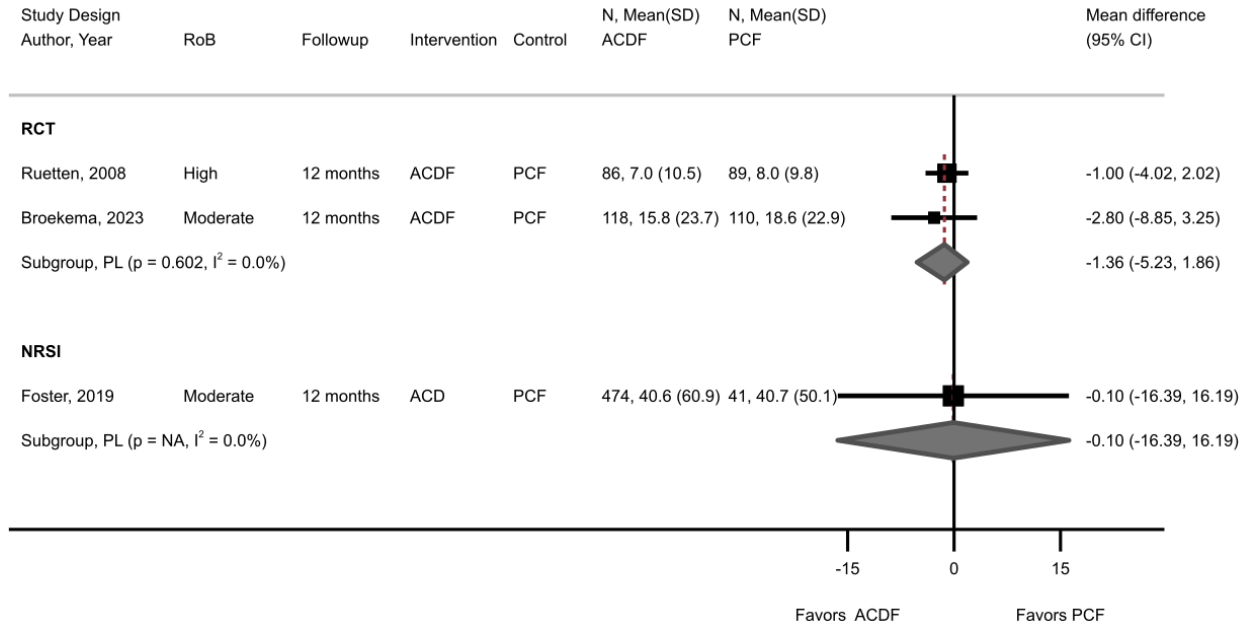
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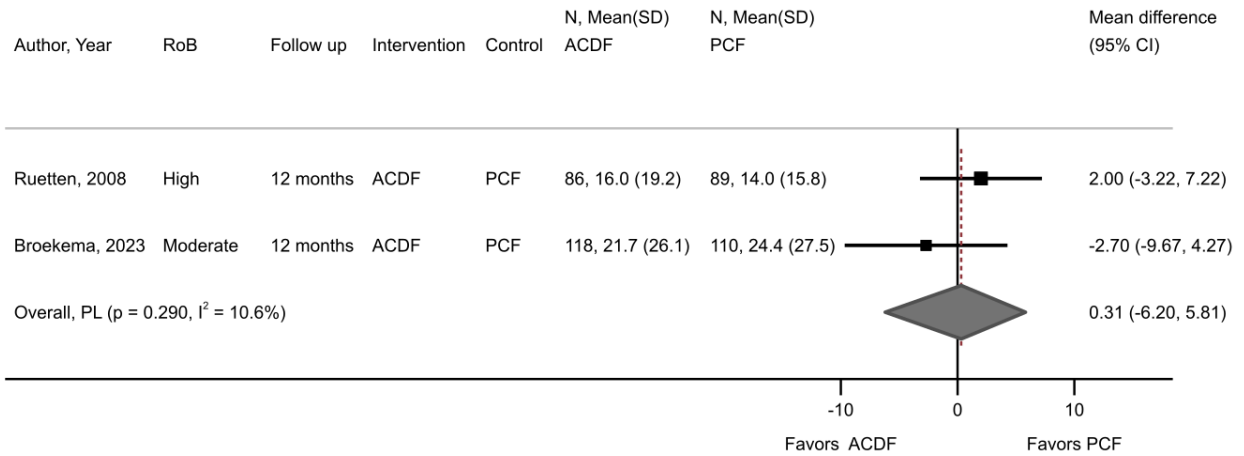
Appendix F. Meta-Analysis

Figure F-1. Effects of ACD or ACDF vs. PCF on VAS scores, arm pain



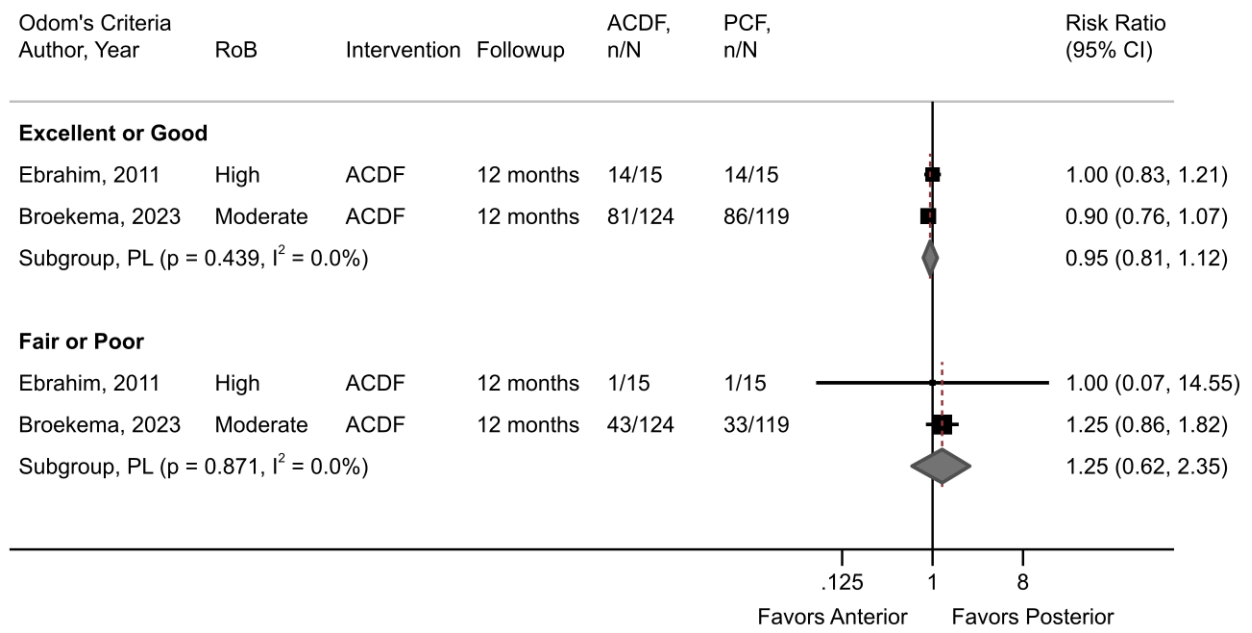
ACD = anterior cervical discectomy; ACDF = anterior cervical discectomy and fusion; CI = confidence interval; PCF = posterior cervical fusion; PL = profile likelihood; RoB = risk of bias; SD = standard deviation; VAS = visual analogue scale

Figure F-2. Effects of ACDF vs. PCF on VAS scores, neck pain



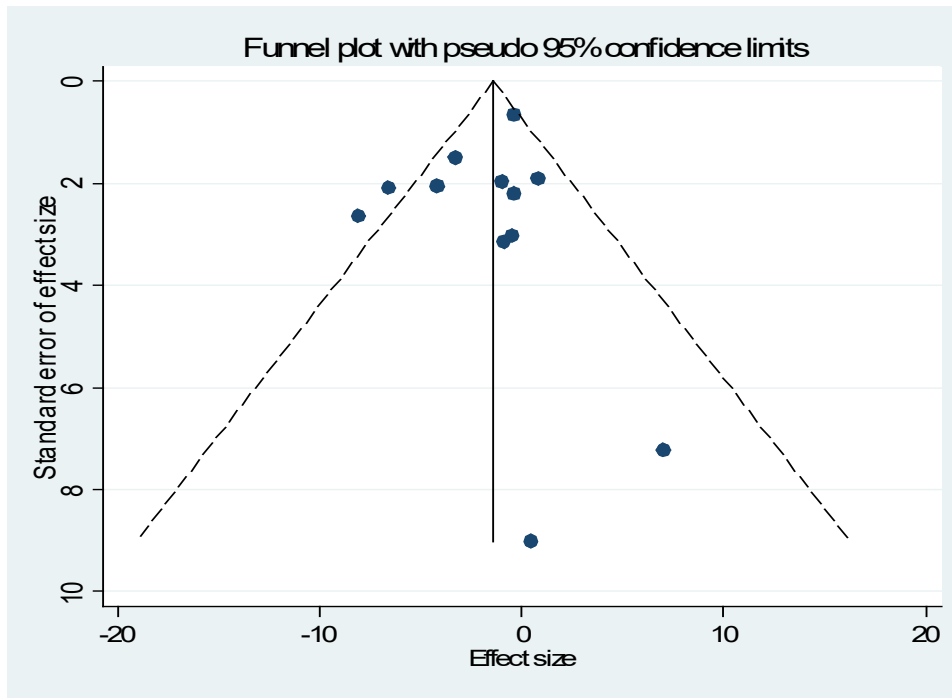
ACDF = anterior cervical discectomy and fusion; CI = confidence interval; PCF = posterior cervical fusion; PL = profile likelihood; RoB = risk of bias; SD = standard deviation; VAS = visual analogue scale

Figure F-3. Odom's criteria: anterior versus posterior approaches



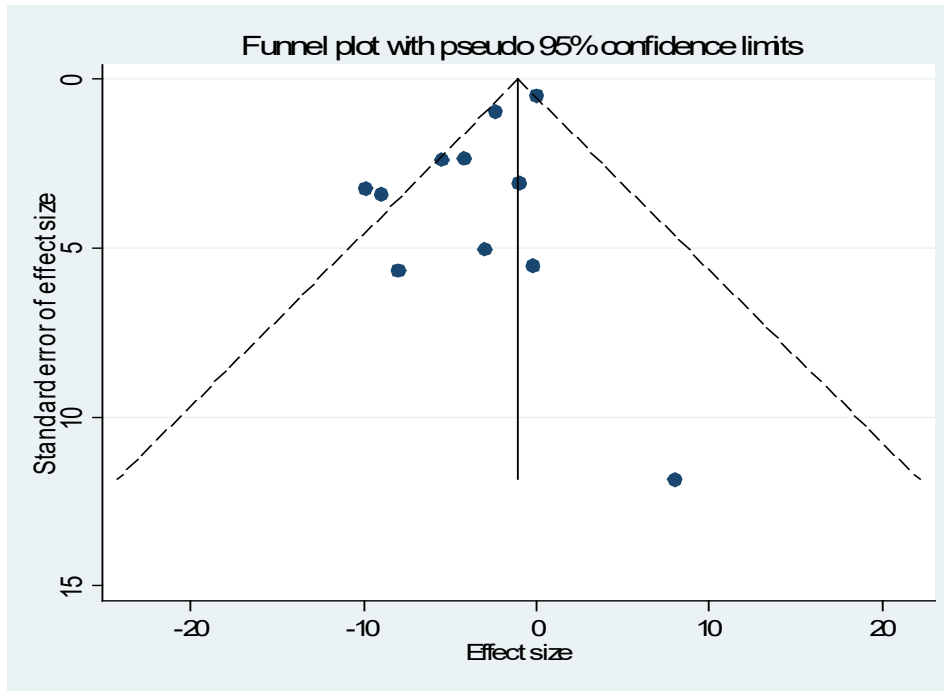
ACDF = anterior cervical discectomy and fusion; CI = confidence interval; PCF = posterior cervical fusion; PL = profile likelihood; RoB = risk of bias

Figure F-4. Funnel plot for intermediate term NDI scores after 1-level ACDF



ACDF = anterior cervical discectomy and fusion; NDI = Neck Disability Index

Figure F-5. Funnel plot for intermediate term neck pain scores after 1-level ACDF



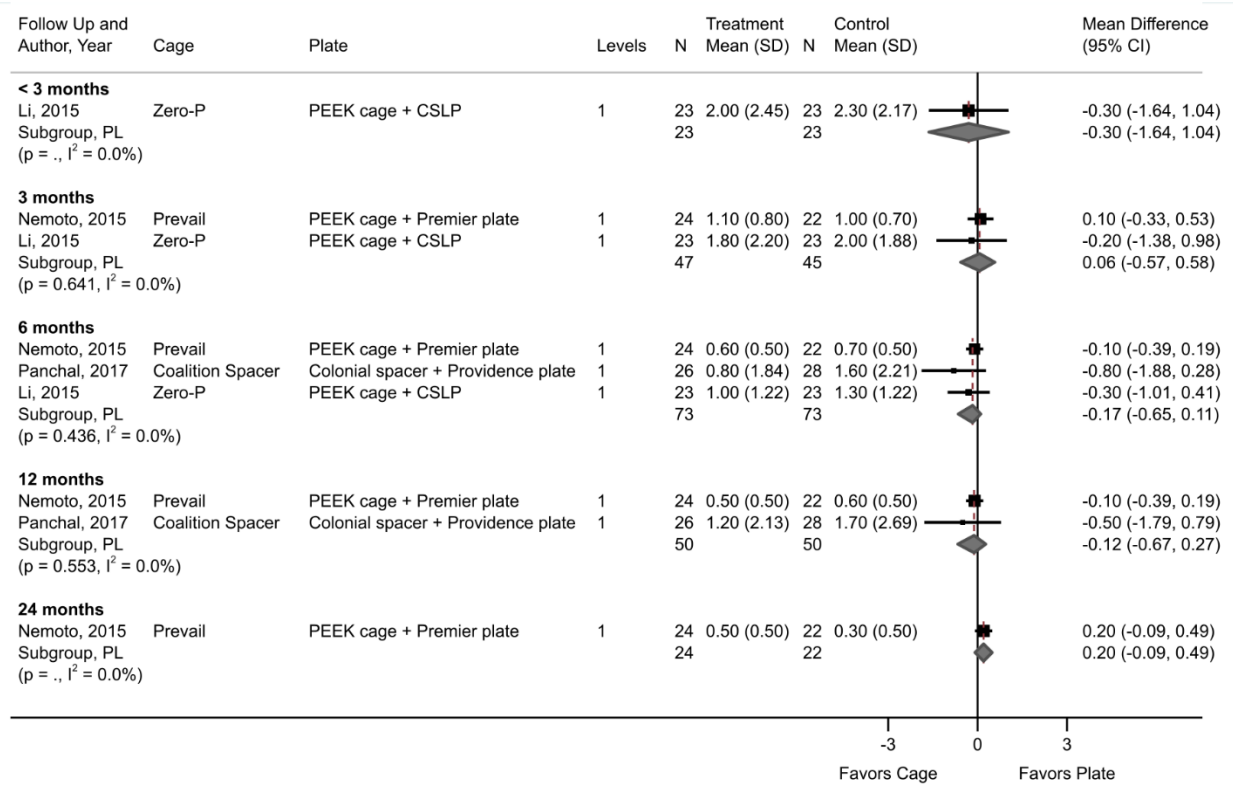
ACDF = anterior cervical discectomy and fusion

Figure F-6. Effects of cage versus plate, unspecified neck pain, 1-level ACDF

Follow Up and Author, Year	Cage	Plate	Levels	Treatment N	Treatment Mean (SD)	Control N	Control Mean (SD)	Mean Difference (95% CI)
3 months								
Nemoto, 2015	Prevail	PEEK cage + Premier plate	1	24	2.90 (1.10)	22	2.70 (0.80)	0.20 (-0.35, 0.75)
Subgroup, PL (p = ., I ² = 0.0%)				24		22		0.20 (-0.35, 0.75)
6 months								
Nemoto, 2015	Prevail	PEEK cage + Premier plate	1	24	1.60 (0.60)	22	1.50 (0.70)	0.10 (-0.28, 0.48)
Panchal, 2017	Coalition Spacer	Colonial spacer + Providence plate	1	26	3.20 (3.60)	28	3.00 (3.10)	0.20 (-1.60, 2.00)
Subgroup, PL (p = 0.915, I ² = 0.0%)				50		50		0.10 (-0.47, 0.71)
12 months								
Nemoto, 2015	Prevail	PEEK cage + Premier plate	1	24	1.50 (0.60)	22	1.30 (0.60)	0.20 (-0.15, 0.55)
Panchal, 2017	Coalition Spacer	Colonial spacer + Providence plate	1	26	2.80 (2.80)	28	3.20 (3.10)	-0.40 (-1.97, 1.17)
Subgroup, PL (p = 0.466, I ² = 0.0%)				50		50		0.17 (-0.54, 0.64)
24 months								
Nemoto, 2015	Prevail	PEEK cage + Premier plate	1	24	0.90 (0.80)	22	1.10 (0.70)	-0.20 (-0.63, 0.23)
Subgroup, PL (p = ., I ² = 0.0%)				24		22		-0.20 (-0.63, 0.23)

ACDF = anterior cervical discectomy and fusion; CI = confidence interval; PEEK = polyetheretherketone; PL = profile likelihood; SD = standard deviation

Figure F-7. Effects of cage versus plate, arm pain, 1-level ACDF



ACDF = anterior cervical discectomy and fusion; CI = confidence interval; PEEK = polyetheretherketone; PL = profile likelihood; SD = standard deviation.

Appendix G. Strength of Evidence

G1.1 Strength of Evidence Assessment

The EPC strength of evidence (SOE) rating for each body of evidence was assessed as high, moderate, low, or insufficient, using the approach described in the AHRQ Methods Guide,² based on study limitations, consistency, directness, precision, and reporting bias.

- Study Limitations (low, moderate, or high)
- Directness (Direct or Indirect)
- Consistency (Consistent, Inconsistent, or Unknown)
- Precision (Precise or Imprecise)
- Reporting Bias (Suspected or Undetected)

These criteria were applied regardless of whether evidence was synthesized quantitatively or qualitatively. The I^2 statistic was used to help assist consistency in pooled analyses; The confidence intervals surrounding effect estimates were reviewed for clear benefit, no effect, and clear harms to aid in assessing precision. We considered evidence from both randomized trials and nonrandomized studies in determining strength of evidence with greater weight given to randomized studies. Strength of evidence ratings reflected our confidence or certainty in the findings. Strength of evidence was considered insufficient when evidence was lacking, sparse, or too conflicting such that we were unable to draw conclusions. SOE was initially assessed by one researcher and confirmed by a second. Based on the assessments for each domain, an overall strength of evidence grade was assigned to each outcome, as defined in the AHRQ Methods Guide.²

Table G-1. Strength of evidence definitions

Grade	Definition
High	We are very confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has few or no deficiencies. We believe that the findings are stable, i.e., another study would not change the conclusions.
Moderate	We are moderately confident that the estimate of effect lies close to the true effect for this outcome. The body of evidence has some deficiencies. We believe that the findings are likely to be stable, but some doubt remains.
Low	We have limited confidence that the estimate of effect lies close to the true effect for this outcome. The body of evidence has major or numerous deficiencies (or both). We believe that additional evidence is needed before concluding either that the findings are stable or that the estimate of effect is close to the true effect.
Insufficient	We have no evidence, we are unable to estimate an effect, or we have no confidence in the estimate of effect for this outcome. No evidence is available or the body of evidence has unacceptable deficiencies, precluding reaching a conclusion.

Table G-1 taken from page 18 of the AHRQ Methods Guide.²

G2.1 Strength of Evidence Tables

Key Questions 1 and 10 had no eligible studies to assess.

Table G-2. Key Question 2: surgery versus conservative treatment

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Neurologic Function mJOA response mJOA scores	1 RCT (N=68) ⁸⁻¹⁰ 1 NRSI (N=80) ¹¹	High	Inconsistent	Direct	Imprecise	Undetected	1 RCT (N=66), mJOA response at 36 months: 61% vs. 73%, RR 0.83, 95% CI 0.59 to 1.18 1 RCT (N=47), mJOA scores at 10 years: 14 vs. 15, p=0.114 1 NRSI (N=40), Mild to moderate myelopathy at 12 months, mJOA scores: 15.4 vs. 14.2, p=0.03; at 36 months: 16.1 vs. 15.2, p=0.013 1 NRSI (N=40), Severe myelopathy at 12 months, mJOA: 11.5 vs. 8.6 p=0.001; at 36 months: 12.45 vs. 8.65, p<0.001	Insufficient
Adverse Events: Neurological worsening on mJOA	1 NRSI (N=80) ¹¹	High	Unknown	Direct	Imprecise	Undetected	0% vs. 5%, p=0.294	Insufficient

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
General Function 10-meter Walk Test ADL improvement Self-reported improved disease course SF-12	1 RCT (N=68) ⁸⁻¹⁰ 1 NRSI (N=80) ¹¹	High	Consistent	Direct	Imprecise	Undetected	<p>1 RCT (N=66), 10-meter walk test, Surgery (baseline: 7.9 seconds; 6 months: 8.7 sec; 12 months: 9.9 sec; 24 months: 11.7 sec; 36 months: 9.4 sec) vs. Conservative treatment (baseline: 7.4 sec; 6 months: 7.2 sec; 12 months: 7.4 sec; 24 and 36 months: 7.5 sec)</p> <p>1 NRSI (N=40), 10-meter walk test, Mild to moderate myelopathy: no differences between treatments</p> <p>1 NRSI (N=40), 10-meter walk test, Severe myelopathy at 12 months: 11.4 seconds vs. 14.4 seconds, p=0.005; 36 months 10.3 seconds vs. 14.1 seconds, p=0.002)</p> <p>1 RCT (N=66) improvement in ADLs at 6 months: 20% vs. 5.9%; worsening in ADLs: 20% vs. 8.8%, no differences at 12, 24, or 36 months</p> <p>1 RCT (N=66) at 6 months, improvement in disease course: 61% vs. 20%, p=0.001</p> <p>1 NRSI (N=40), SF-12 PCS and MCS, Mild and moderate myelopathy: PCS: 37.4 vs. 37.95, p=0.75; MCS: 47.5 vs. 46.7, p=0.78</p> <p>1 NRSI (N=40), SF-12 PCS and MCS, Severe myelopathy: PCS: 53.3 vs. 26.85, p<0.001; MCS: 61.2 vs. 31.4, p<0.001</p>	Insufficient

ADL = activities of daily living; MCS=Mental Component Score; mJOA=modified Japanese Orthopaedic Association score; NRSI = nonrandomized studies of interventions; PCS=Physical Component Score; RCT=randomized controlled trial; SF-36/12=Short-form 36 or 12 questionnaire

Table G-3. Key Question 3: surgery versus physiotherapy versus collar

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Pain VAS	1 RCT (N=81) ^{12,13}	Moderate	Unknown	Direct	Imprecise	Undetected	<p>N=54, 0-100 VAS current pain, surgery vs. collar 14-16 weeks: 27 vs. 48, p<0.01</p> <p>N=81, current pain, surgery vs. physiotherapy vs. collar, 16 months: 30 vs. 39 vs. 35, p>0.05</p> <p>N=54, 0-100 VAS worst pain, surgery vs. collar 14-16 weeks: 43 vs. 64, p<0.01</p> <p>N=81, worst pain, surgery vs. physiotherapy vs. collar, 16 months: 42 vs. 53 vs. 52, p>0.05</p>	Insufficient
Neurologic Function Muscle strength Parathesias Improvement in sensory loss	1 RCT (N=81) ^{12,13}	Moderate	Unknown	Direct	Imprecise	Undetected	<p>N=54, at 14-16 weeks, muscle strength, surgery better than physiotherapy in: pinch grip, elbow extension, shoulder internal rotation vs. physiotherapy; surgery better than collar in wrist and elbow flexion; at 16 months surgery better than physiotherapy in wrist and elbow extension, shoulder abduction, and shoulder internal rotation; no differences between surgery and collar or between physiotherapy and collar</p> <p>At 14-16 weeks, no difference in improvement in paresthesias (52% vs. 45% vs. 37%, p>0.05; at 16 months, remained no difference (51% vs. 67% vs. 66%, p>0.05)</p> <p>At 14-16 weeks, greater improvement in sensory loss with surgery vs. physiotherapy or collar (41% vs. 15% vs. 15%, p<0.05); no difference between treatments at 16 months (27% vs. 14% vs. 15%, p>0.05)</p>	Insufficient

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
General Function Disability Rating Index	1 RCT (N=81) ^{12,13}	Moderate	Unknown	Direct	Imprecise	Undetected	DRI 0-100, 14-16 weeks: surgery better than collar on dressing and completing heavy work (p<0.05); Physiotherapy better than collar on ability to walk, sit for a long time, and complete heavy work (P<0.05) At 16 months: Surgery better than physiotherapy or collar on ability to complete heavy work (p<0.05)	Insufficient
Adverse Events	No studies	NA	NA	NA	NA	NA	NA	NA

DRI = disability rating index; NA = not applicable; RCT = randomized controlled trial; VAS = visual analogue scale

Table G-4. Key Question 4: surgery (laminoplasty) plus add-on therapy versus surgery alone

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Add-on Therapy: Pain (Collar) Laminoplasty	2 RCTs (N=125) ^{14,15}	Moderate	Consistent	Direct	Imprecise	Undetected	Similar VAS scores (0-10) when adding a collar at 6 months (1.3 vs. 1.3; data NR in one trial), and 12 months (mean score 1.7 vs. 1.7 in one trial; mean change from baseline 0.19 vs. -0.04 in another)	Low
Add-on Therapy: Pain (Exercise) Laminoplasty	1 RCT (N=65) ¹⁶	Moderate	Inconsistent	Direct	Imprecise	Undetected	Similar difference in mean VAS scores (0-100 scale) for neck pain and stiffness at 2 weeks and 3 months postoperative between muscle-preserving laminoplasty with exercises versus laminoplasty alone (25.3 vs. 20.6)	Insufficient
Add-on Therapy: General Function (Collar) Laminoplasty	2 RCTs (N=125) ^{14,15}	Moderate	Consistent	Direct	Imprecise	Undetected	Similar mean change or absolute NDI scores at 6 months (22.4 vs. 23.1) and 12 months (20.8 vs. 22.9). Greater mean change in SF-36 MCS scores adding collar at 6 months (41.0 vs. 48.3, p<0.05) and 12 months (48.3 vs. 48.9; data NR in one trial). Similar SF-36 PCS scores at 6 months (36.3 vs. 36.0) and 12 months (39.0 vs. 36.7; data NR in one trial).	Low
Add-on Therapy: Neurological Function (Collar) Laminoplasty	2 RCTs (N=125) ^{14,15}	Moderate	Consistent	Direct	Precise	Undetected	Similar mJOA scores at 6 weeks (13.8 vs. 13.3) in laminoplasty with postoperative collar, with no difference found up to 12 months (14.1 vs. 14.5 in one trial; 11.1 vs. 11.8 in another)	Low

MCS = mental component summary score; mJOA = Modified Japanese Orthopaedic Association Scale; NDI = Neck Disability Index; NR = not reported; PCS = physical component summary score; RCT = randomized controlled trial; SF-36 = 36-Item Short Form Health Survey; VAS = visual analogue scale

Table G-5. Key Question 4: surgery (ACDF) plus add-on therapy versus surgery alone

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Add-on Therapy: Fusion (PEFM) ACDF	1 RCT (N=323) ¹⁷	Moderate	Inconsistent	Indirect	Imprecise	Undetected	Improved rates of fusion at 6 months adding PEFM to ACDF (83.6% vs. 68.6%, p=0.0065); similar rates of fusion with PEFM at 12 months (92.8% vs. 86.7%)	Low
Add-on Therapy: Fusion (Collar) ACDF	1 RCT (N=33) ¹⁸	Moderate	Inconsistent	Indirect	Imprecise	Undetected	Similar rates of fusion adding post-op collar to ACDF vs. no collar at 24 months (100% vs. 100%)	Insufficient
Add-on Therapy: Pain (PEFM) ACDF	1 RCT (N=323) ¹⁷	Moderate	Inconsistent	Indirect	Imprecise	Undetected	Similar VAS scores (0-10) with PEFM added to ACDF at 6 months (2.4 vs. 2.3) and 12 months (2.2 vs. 2.0)	Low
Add-on Therapy: General Function (Collar) ACDF	1 RCT (N=33) ¹⁸	Moderate	Inconsistent	Indirect	Imprecise	Undetected	Similar mean change in NDI scores adding collar to ACDF at 6 months (-6.42 vs. -5.24) and 24 months (-7.94 vs. -9.93). Similar mean change in SF-36 MCS scores adding collar at 6 months (5.01 vs. 4.69) and 24 months (7.44 vs. 5.69). Greater mean change in SF-36 PCS scores adding collar at 6 months (10.02 vs. 3.24); similar mean change at 24 months (8.11 vs. 6.28).	Insufficient
Add-on Therapy: General Function (PEFM) ACDF	1 RCT (N=323) ¹⁷	Moderate	Inconsistent	Indirect	Imprecise	Undetected	Similar mean change or absolute NDI scores adding PEFM to ACDF at 6 months (31.0 vs. 23.0) and 12 months (25.6 vs. 22.8)	Low

ACDF = anterior cervical discectomy and fusion; CI = confidence interval; MCS = Mental Component Score; mJOA = modified Japanese Orthopaedic Association score; NDI = Neck Disability Index; NR = not reported; PCS = Physical Component Score; PEFM = pulsed electromagnetic field; RCT = randomized controlled trial; SF-36/12 = 36- or 12-Item Short Form Health Survey; VAS = visual analog scale

Table G-6. Key Question 5. anterior versus posterior procedures in ≤ 2 levels in patient with radiculopathy

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect Anterior Versus Posterior
Fusion	1 RCT (N=30) ¹⁹	High	Unknown	Imprecise	Undetected	Insufficient	No patient had evidence of instability on x-rays; criteria for stability or fusion were not described
Pain, Neck Pain scores Discharge	1 RCT(N=30) ¹⁹	High	Unknown	Imprecise	Undetected	Insufficient	MD -3.13, 95% CI -4.52 to 1.74, p<0.001 Authors reported p-value and confidence interval do not coincide.
Pain, Pain scores Short-term (3 months, 6 months)	1 RCT (N=175) ²⁰ 1 NRSI (N=688) ²¹ (moderate)	Moderate	Consistent	Imprecise (no information on variation from studies)	Undetected	Low	3 months RCT: VAS arm pain (0-100), mean: 10 vs. 11; MD -1 VAS neck pain (0-100), mean: 19 vs. 15; MD 4 NASS pain (0-6), mean: 1.5 vs. 1.4; MD 0.1 NRSI (N=688) Arm VAS (0-10) means (4.20 vs. 3.82, MD 0.38, p>0.05) 6 months RCT: VAS arm pain (0-100), mean: 8 vs. 9; MD -1 VAS neck pain (0-100), mean: 19 vs. 17; MD 2 NASS pain (0-6), mean: 1.8 vs. 1.6; MD 0.2 Arm VAS (0-10) Neck VAS (0-10) NASS (0-6)

<p>Pain, Arm or Neck pain scores <i>Intermediate term (12 months 24 months)</i></p>	<p>1 RCT (N=175) (high) 1 RCT (N=243)²² (moderate)</p> <p>1 NRSI (N=688)²³ (moderate)</p> <p>1 NRSI (N=70)²¹ (high)</p>	<p>Moderate</p>	<p>Consistent</p>	<p>Imprecise (no information on variation from studies)</p>	<p>Undetected</p>	<p>Low</p>	<p>12 months Moderate RCT VAS arm pain (0-100), MD – 2.80, 95% CI, -8.85 to 3.25 VAS neck pain (0-100), MD -2.70, 95% CI -9.67 to 4.27</p> <p>1 RCT: VAS arm pain (0-100), mean: 7 vs. 8; MD -1 VAS neck pain (0-100), mean: 16 vs. 14; MD 2</p> <p>RCTs pooled: VAS arm pain (0-100), Pooled MD -1.36, 95% CI -5.23 to 1.86, I²= 0%.) VAS neck pain (0-100), Pooled MD 0.31, 95%CI -620 to 5.81, I²=10.6%</p> <p>NASS pain (0-6), mean: 1.7 vs. 1.8; MD -0.1</p> <p>NRSI N=688 Arm VAS (0-10) (4.06 vs. 4.07, MD 0.01, p>0.05)</p> <p>NRSI (N=70) VAS score (0-10 scale, arm or neck pain not specified) Mean, 95%CI 2.6 (1.7 to 3.4) vs. 3.0 (1.9 to 4.2), p=0.4</p> <p>24 months RCT: VAS arm pain (0-100), mean: 8 vs. 7; MD 1 VAS neck pain (0-100), mean: 17 vs. 16; MD 1 NASS pain (0-6), mean: 1.5 vs. 1.4; MD 0.1</p>
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Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect Anterior Versus Posterior
							NRSI (N=688) Arm VAS (0-10) 3.85 vs. 4.48, MD -0.63, p>0.05
Pain Success VAS Pain (0-100 scale) (41 point improvement in arm pain, 26 point improvement in neck pain,	1 RCT (N=243) ²² (moderate)	Moderate	Unknown	Imprecise (no information on variation from studies)	Undetected	Low	VAS arm pain 60% vs. 54%, VAS neck pain 62% vs. 52% Authors report groups were comparable in proportion responding
Function, Neurologic	1 RCT (N=175) ²⁰	High	Unknown	Imprecise (no information on variation)	Undetected	Insufficient	NASS neurology scores (0-6 scale) Means similar for ACDF and PCF (range, MD -0.2 to 0.2); no detail reported

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect Anterior Versus Posterior
Function, General Odom's Criteria NDI "success (improvement) and scores" Core Outcome Measures Index-neck (COMI) Pain Disability Questionnaire (PDQ) Functional status component	2 RCT (N=273) ^{19,22} 1 NRSI (N=688) ²³ 1 NRSI (N=70) ²¹	Moderate	Unknown	Imprecise	Undetected	Low	Odom's Criteria (2 RCTs) Excellent or good 68.3% vs. 74.6%, RR 0.95, 95%CI 0.81 to 1.12, I ² = 0%) NDI (0-100), 12 months Improvement:63% vs. 66% Scores: mean change scores on MD -1.2 , 95% CI -5.8 to 3.5 NRSI N=688 (appear to be unadjusted estimates) COMI-neck scores (0-10 scale) Mean change:3 months (2.38 vs. 2.31, p=0.88) and 6 months (2.94 vs. 2.67, p=0.55) 24 months the mean scores were 4.16 vs. 4.72, p>0.05; COMI-neck success (response) 3 months (50% vs. 56%, RR 0.89, 95% CI 0.65 to 1.24), 12 months (59% vs. 58%, RR 1.02, 95% CI 0.76 to 1.36), and 24 months (57% vs. 50%, RR 1.14, 95% CI 0.71 to 1.83) NRSI N=70 PDQ (0-90, unadjusted estimates) functional status subscale 31.3 vs. 43.2, MD – 11.9, p=0.30 PDQ total score (52.8 vs. 69.6, p=0.50)

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect Anterior Versus Posterior
Quality of Life – 12 months	1 RCT (N=243) ²² 1 NRSI (N=70) ²¹	Moderate	Unknown	Imprecise	Undetected	Low	EQ-5D/QALY (Scale 0 to 1) RCT: Success (Improvement of 0.24): 38% vs. 38%, Scores: MD -0.01, 95% CI -0.06 to 0.10 (change scores) NRSI: ACDF (0.69, 95% CI 0.61 to 0.77) versus PCF (0.72, 95% CI 0.64 to 0.80), p=0.60)
Reoperation (any time)	4 RCTs (N=519) ^{19,20,22,24} 1 NRSI (N=328) ²⁵	Moderate	Consistent	Imprecise	Undetected	Low	RCTs: RR 0.71, 95% CI 0.39 to 1.32, I ² =0% NRSI: RR 0.74, 95% CI 0.30 to 1.32)

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect Anterior Versus Posterior
New neurological deficit or neurologic complication	4 RCT (N=519) ^{19,20,22,24} 1 NRSI (N=70) ²¹ 1 NRSI (N=46,598) ²⁶	Moderate	Consistent	Imprecise	Undetected	Low	<p>1 RCT (n=243) New radicular symptoms 3.2% vs. 0.8%, RR 3.84, 95%CI 0.43 to 33.85) Persistent radicular symptoms (1.6% vs. 6.7%, RR 0.24, 95% CI 0.05 to 1.11</p> <p>1 RCT (N=72) New weakness 8% vs. 14%, RR 0.59, 95% CI 0.14 to 2.40 New numbness 6% vs. 9%, RR 0.66, 95% CI 0.12 to 3.68</p> <p>1 RCT (N=30) Horner's Syndrome 0% vs. 0% 1 RCT (175) Myelon damage resulting in any paralysis: 0% vs. 0%</p> <p>1 NRSI (N=70) C5 Palsy: Anterior (NR) vs. 1 patient (PCF)</p> <p>1 NRSI (N=46,598) CNS complication: MD 4 per 10,000, 95% CI -14 to 22 per 10,000, p=0.68</p>
Mortality	1 RCT (N=72) ²⁴ 1 NRSI (N=46,598) ²⁶	Moderate	Unknown	Imprecise (RCT) Precise (NRSI)	Undetected	Insufficient	<p>RCT: 0% vs. 0%</p> <p>NRSI (N=46,598) 30-day mortality for ACDF versus PCF (MD 1 events per 10,000 cases, 95% CI 0.0 to 2 per 10,000 cases, p=0.012).</p>

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect Anterior Versus Posterior
Serious AEs	4 RCTs (N=519) ^{19,20,22,24}	Moderate	Consistent	Imprecise	Undetected	Insufficient	<p>1 RCT (N= 243): surgery-related adverse events 6% in both groups (not specified)</p> <p>AEs during hospitalization anaphylactic reaction to antibiotics n=1 ACDF wound hematoma not requiring surgery, n=1 PCF pulmonary embolism, n=1 ACDF</p> <p>AEs requiring hospitalization wound problems 0.8% vs. 1.7%, cardio-thoracic problems 0.08% vs. 2.5%).</p> <p>Slight cage subsidence, n=1 (no reoperation needed)</p> <p>Three RCTs reported that there were no serious adverse events for any patients; however, studies were likely underpowered to detect rare events</p>
Specific AEs 30 days post-operatively	1 NRSI (N=46,598) ²⁶	Moderate	Unknown	Precise	Undetected	Insufficient	<p>Vascular injury MD 2 per 10,000 cases, 95% CI 1 to 3 per 10,000 cases, p=0.001</p> <p>CSF fluid leak MD 2 per 10,000 cases, 95% CI 1 to 3 per 10,000 patients, p=0.002</p> <p>Deep vein thrombus (9 per 10,000 cases, 95%CI 2 to 16 per 10,000 patients, p=0.01</p> <p>Pulmonary embolism 2 per 10,000, 95% CI -9 to 12 per 10,000 cases, p=0.75</p>

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect Anterior Versus Posterior
Unresolved dysphagia at 12 months	1 RCT (N=243) ²²	Moderate	Unknown	Imprecise	Undetected	Insufficient	1 case reported in the ACDF group

AE = adverse event; CSF = cerebral spinal fluid; COMI = Core Outcome Measures Index-neck; CI = confidence interval; MD = mean difference; NRSI = nonrandomized study of intervention; PDQ = Pain Disability Questionnaire; RCT = randomized controlled trial; RR = risk ratio

Table G-7. Key Question 6: anterior versus posterior procedures in ≥ 3 levels

Outcome Timing	Number of Studies (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect
Fusion <i>Intermediate term</i>	1 NRSI (N=3,714) ²⁷	Moderate	Unknown	Imprecise	Undetected	Insufficient	Pseudarthrosis , 12 months: OR 2.43, 95% CI 1.96 to 3.01 (propensity-score matching)
Pain Neck Pain scores <i>Short term</i>	1 RCT (N=32) ²⁸	High	Unknown	Imprecise	Undetected	Insufficient	VAS pain (0-10 scale) 3 months: MD -0.10, 95% CI -0.46 to 0.26 6 months: MD 0, 95% CI -0.18 to 0.18
Pain Neck Pain scores <i>Intermediate term</i>	1 RCT (N=32) ²⁸ 1 NSRI (N=245) ²⁹	RCT (High) NRSI (Moderate)	Consistent	Imprecise	Undetected	Low	VAS/NRS pain (0-10 scale) 1 RCT 12 months: MD 0.10, 95% CI -0.23 to 0.43) 15 months: MD -0.10, 95% CI -0.44 to 0.24 1 NRSI 12 months: adjusted OR 0.67, 95% CI 0.37 to 1.21
Pain Arm Pain scores <i>Intermediate term</i>	1 NSRI (N=245) ²⁹	Moderate	Unknown	Imprecise	Undetected	Insufficient	NRS pain (0-10 scale) , 12 months: adjusted OR 0.99, 95% CI 0.51 to 1.93
Function, Neurologic JOA <i>Short term</i>	1 RCT (N=32) ²⁸	High	Unknown	Imprecise	Undetected	Insufficient	JOA scores (0-17) 3 months: MD -0.40, 95% CI -1.76 to 0.96 6 months: MD 0.20, 95% CI -1.14 to 1.54
Function, Neurologic mJOA or JOA, Nurick <i>Intermediate term</i>	1 RCT (N=32) ²⁸ 2 NRSIs (N=509) ^{29,30}	RCT (High) NRSI (Moderate)	Consistent	Imprecise	Undetected	Low	JOA/mJOA scores (0-18) , 12 months 3 studies, pooled MD 0.16, 95% CI -0.15 to 0.51, I ² =50% Nurick scores (0-5) , 12 months 1 NRSI (N=264) MD in change scores 0.19, 95% CI -0.20 to 0.58

Outcome Timing	Number of Studies (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect
Function, General NDI, SF-36 PCS and MCS <i>Intermediate term</i>	2 NRSIs (N=509) ^{29,30}	Moderate	Consistent	Imprecise	Undetected	Low	NDI scores (scale unclear), 12 months 1 NRSI: (N=264): MD in change scores -0.97, 95% CI -7.15 to 5.21 1 NRSI (N=245): adjusted OR 0.76, 95% CI 0.42 to 1.37 SF-36 scores (0-100), 1 NRSI (N=264), 12 months PCS: MD in change scores -1.90, 95% CI -5.30 to 1.50 MCS: MD in change scores 0.42, 95% CI -2.30 to 3.14
Quality of Life <i>Intermediate term</i>	1 NSRI (N=245) ²⁹	Moderate	Unknown	Imprecise	Undetected	Insufficient	EQ5D scores, 12 months Adjusted OR 1.36, 95% CI 0.76 to 2.44, referent=ACDF
Reoperation <i>Any time, longest followup</i>	7 NRSIs (N=27,579) ^{27,29,31-35}	Moderate	Inconsistent	Imprecise	Undetected	Insufficient	ACDF versus laminoplasty 2 NRSIs (N=3,406), 1 to 24 months 5.4% (92/1703) vs. 6.2% (105/1703) Pooled RR 0.87, 95% CI 0.59 to 1.79, I ² =0% ACDF versus PCDF 6 NRSIs (N=24,355), 1 to 60 months 10.1% (1,344/13,354) vs. 11.8% (1,293/11,001) Pooled RR 0.79, 95% CI 0.47 to 1.35, I ² =96.5% Excluding outlier study at 60 months (Joo, 2022) 5 NRSIs (N=20,641), 1-18 months 7.4% (856/11,497) vs. 10.4% (953/9,144), Pooled RR 0.59, 95% CI 0.42 to 0.95, I ² =82.4%

Outcome Timing	Number of Studies (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect
New neurological deficit	1 RCT (N=32) ²⁸ 6 NRSIs (N=37,095) ^{27,29-32,36}	High (RCT) Moderate (NRSI)	Consistent	Imprecise	Undetected	Low	<p>RCT: no cases of postoperative worsening of myelopathy or C5 root palsy</p> <p>Central nervous system complications 1 NRSI (N=3,042), 3 months <0.7% (<11/1521) vs. 0.9% (14/1521), p=NS</p> <p>Neurologic complications 2 NRSIs (N=21,296) Inpatient: 0.35% (24/6942) vs. 0.59% (41/6942), adjusted OR for PCDF 1.7, 95% CI 1.0 to 2.8 1 month: 1.1% (55/4895) vs. 1.8% (45/2517), OR for PCDF 1.6, 95% CI 1.08 to 2.38</p> <p>New neurological or motor deficit 2 NRSIs (N=209), 12 months 4.1% (7/169) vs. 3.2% (3/95), RR 1.31, 95% CI 0.35 to 4.95 2% (4/163) vs. 0% (0/82)</p> <p>Postoperative coma 1 NRSI (N=12,248) 0.4% (27/6124) vs. 0.6% (34/6124), OR 1.26 for PCDF, 95% CI 0.75 to 1.77</p>

Outcome Timing	Number of Studies (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect
Mortality	4 NRSIs (N=27,305) ^{27,34-36}	Moderate	Consistent	Imprecise	Undetected	Low	<p>ACDF vs. laminoplasty at 1 month: 1 NRSI (N=364) 0% (0/182) vs. 0.05% (1/182) RR 0.33, 95% CI 0.01 to 8.13</p> <p>ACDF vs. PCDF at discharge to 1 month 3 NRSIs (N=14,875) 0.3% (22/7431) vs. 0.3% (25/7444) Pooled RR 0.96, 95% CI 0.25 to 1.81, I²=17.8%</p> <p>ACDF vs. PCDF at 3 months 1 NRSI (N=12,248) 0% (0/6124) vs. 0% (0/6124)</p> <p>Studies other than the largest administrative data study (N=13,884) were likely underpowered to detect rare events.</p>
Severe dysphagia	2 NRSIs (N=609) ^{29,35}	Moderate	Consistent	Imprecise	Undetected	Low	<p>Dysphagia requiring NG tube (1 NRSI): 1% (2/163) vs. 0% (0/82), p=0.31</p> <p>Unplanned readmission due to dysphagia (1 NRSI): 0.5% (1/182) vs. 0% (0/182), p=NR</p>

Serious AEs	1 RCT (N=32) ²⁸ 9 NRSIs (N=41,982) ^{27,29-36}	High (RCT) Moderate (NRSI)	Inconsistent	Imprecise	Undetected	Low	<p>RCT Intraoperative dural tear: 5.9% (1/17) vs. 11.8% (2/17), RR 0.50, 95% CI 0.05 to 5.01 No cases of instrumentation failure or malposition, infection or hematoma</p> <p>Deep vein thrombosis/pulmonary embolism 8 NRSIs (N=41,718), consistent results Range, 0% to 2.3% vs. 0% to 4.3% 4 studies found PCDF associated with higher odds of DVT/PE (range of ORs, 1.8 to 3.7)</p> <p>Stroke/cerebrovascular events 3 NRSIs (N=13,421), inconsistent results 0% (0/182) vs. 0% (0/364); 1.8% (6/307) vs. 0% (0/320), p=0.016; 2.5% (154/6124) vs. 4.2% (255/6124), OR 1.68, 95% CI 1.48 to 1.89</p> <p>Sepsis 3 NRSIs (N=7,302), inconsistent results 1 NRSI: 0.7% (13/1857) vs. 2.5% (46/1857), adjusted OR 3.56, 95% CI 1.96 to 6.91 2 NRSIs (N=3,588), range <0.7% to 1.1 vs. <0.7% to 1.7%, p=NS</p> <p>Surgical site infection 4 NRSIs (N=22,947), consistent results 3 NRSIs (N=22,702): range, 0.8% to 1.0% vs. 2.4% to 4.7%, range of ORs for PCDF 3.1 to 3.7 (p<0.05) 1 NRSI (N=245): 1% (1/163) vs. 1% (1/82), p=0.62</p> <p>Wound dehiscence 4 NRSIs (N=22,947), inconsistent results 2 NRSI (N=19,660): range, 1.3% to 2.7% vs. 0.1% to 0.5%, range of ORs for PCDF 5.6 to 10.8, p<0.05 2 NRSIs (N=509): range 0% to 1% vs. 0% to 1%, p=NS</p>
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Outcome Timing	Number of Studies (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect
							<p>Dural tear/durotomy 2 NRIS (N=891), inconsistent results 1 NRIS (N=627): 9.4% (29/307) vs. 3.2% (10/320), RR 3.02, 95% CI 1.50 to 6.10 1 NRIS (N=264): 0% (0/169) vs. 0/95)</p> <p>Any serious AE (not defined) 1 NRIS (N=3,714): 6.1% (113/1857) vs. 13.0% (242/1857), OR 2.31 for PCDF, 95% CI 1.83 to 2.93</p>

ACDF = anterior cervical discectomy and fusion; AE = adverse event; CI = confidence interval; EQ52 = EuroQOL-5D; MCS = Mental Component Score; mJOA = modified Japanese Orthopaedic Association score; NDI = Neck Disability Index; NRS = Numeric Rating Scale; NS = not significant; OR = odds ratio; PCDF = posterior cervical decompression and fusion; PCS = Physical Component Score; RCT = randomized controlled trial; SF-36/12 = 36- or 12-Item Short Form Health Survey; VAS = visual analog scale

Table G-8. Key Question 7: laminectomy with fusion vs. laminoplasty

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Neurologic function: JOA	2 RCTs (N=46) ^{37,38} 4 observational studies (N=582) ³⁹⁻⁴²	Moderate	Consistent	Direct	Precise	Not detected	No difference between cervical laminoplasty and cervical laminectomy and fusion in JOA scores in the trials (pooled MD -0.03; 95% CI -0.68 to 0.74) or in 3 of 4 observational studies	Moderate
Neurologic function: Nurick grade	2 RCTs (N=46) ^{37,38} 1 observational study (N=266) ⁴⁰	Moderate	Inconsistent	Direct	Imprecise	Not detected	No difference between cervical laminoplasty and cervical laminectomy and fusion in Nurick grade in one trial (1.40 vs. 1.67; p=0.23) but a significant pre-post difference in Nurick grade only among laminoplasty patients in the other trial (numeric values not reported; p<0.05); no difference between groups in the observational study	Low
Pain	2 RCTs (N=46) ^{37,38} 3 observational studies (N=371) ^{39,41,42}	Moderate	Inconsistent	Direct	Imprecise	Not detected	One trial found a moderate benefit in neck pain with laminectomy and fusion (MD -1.33; p<0.05), but no difference in limb pain, while the other trial reported greater improvements in neck and arm pain only in patients undergoing laminoplasty (numeric values not reported; p<0.05 for both outcomes); three observational studies reported no differences in pain between groups	Insufficient
Neck disability: NDI	2 RCTs (N=46) ^{37,38} 2 observational studies (N=357) ^{39,41}	Moderate	Inconsistent	Direct	Imprecise	Not detected	One trial reported no differences in NDI between groups (MD 3.86; p=0.20), while the other reported improved NDI only in patients undergoing laminoplasty (numeric value not reported; p=0.05); two observational studies reported no differences in NDI	Low

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Neurologic function: JOA	2 RCTs (N=46) ^{37,38} 4 observational studies (N=582) ³⁹⁻⁴²	Moderate	Consistent	Direct	Precise	Not detected	No difference between cervical laminoplasty and cervical laminectomy and fusion in JOA scores in the trials (pooled MD -0.03; 95% CI -0.68 to 0.74) or in 3 of 4 observational studies	Moderate
Function: SF-36	1 RCT (N=16) ³⁸ 3 observational studies (N=461) ³⁹⁻⁴¹	Moderate	Inconsistent	Direct	Imprecise	Not detected	One trial reported improvements in SF-36 in patients undergoing laminoplasty only (numeric value not reported; p<0.05); three observational studies reported no differences in SF-12, SF-36, or SF-36 MCS	Low
Reoperation	2 RCTs (N=46) ^{37,38} 4 observational studies (N=582) ³⁹⁻⁴²	Moderate	Consistent	Direct	Imprecise	Not detected	Two trials and four observational studies found no differences in reoperation rates between groups	Moderate
Infection	2 RCTs (N=46) ^{37,38} 4 observational studies (N=582) ³⁹⁻⁴² 1 database study (N=11,860) ⁴³	Moderate	Inconsistent	Direct	Imprecise	Not detected	Two trials and four observational studies found no differences in infection between groups, while one database study found fewer infections (matched OR 0.60; p=0.002) with laminoplasty than laminectomy and fusion	Low
Dysphagia	2 observational studies (N=387) ^{40,42} 1 database study (N=11,860) ⁴⁴	Moderate	Inconsistent	Direct	Imprecise	Not detected	Dysphagia was more common with laminectomy and fusion than laminoplasty in one database study (matched OR 0.77; p=0.01), while two other observational studies reported no association	Low

MCS=Mental Component Score; MD = mean difference; mJOA=modified Japanese Orthopaedic Association score; NDI=Neck Disability Index; PCS=Physical Component Score; RCT=randomized controlled trial; SF-36/12=36- or 12-Item Short Form Health Survey

Table G-9. Key Question 8: C-ADR versus ACDF strength of evidence – single-level interventions

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Pain, Neck pain success Neck pain scores <i>Short-term</i>	Success 2 (N=482) ^{45,46} Pain scores 8 (N=1,789) ⁴⁷⁻⁵⁴	Moderate	Consistent	Precise	Undetected	Moderate	Success 79.0% (230/291) vs. 75.9% (145/191) Pooled RR 1.04, 95% CI 0.93 to 1.17, I ² =0% Pain scores (0-100 VAS) Pooled MD -3.02, 95% CI -5.53 to -0.40, I ² =15.5%
Pain, Neck pain success Neck pain scores <i>Intermediate term</i>	Success 4 (N=948) ^{45,46,55,56} Pain scores 11 (N=1,898) ^{47,48,50,53,55,57-62}	Moderate	Consistent	Precise	Undetected	Moderate	Success 76.4% (418/547) vs. 74.1% (297/401) Pooled RR 1.03, 95% CI 0.95 to 1.12, I ² =0% Pain scores (0-100 VAS) Pooled MD -3.39, 95% CI -6.14 to -1.23, I ² =63.4%
Pain, Neck pain success Neck pain scores <i>Long term</i>	Success 1 (N=232) ⁶³ Pain scores 5 (N=1,195) ^{57,63-66}	Moderate	Unknown (success) Consistent (scores)	Precise	Undetected	Moderate	Success 85.7% (108/126) vs. 78.3% (83/106) RR 1.09, 95% CI 0.97 to 1.24 Pain scores (0-100 VAS) Pooled MD -4.77, 95% CI -7.63 to -1.76, I ² =0%
Pain, Arm pain success ^a Arm pain scores ^b <i>Short-term</i>	Success 2 (N=482) ^{45,56} Pain scores 6 (N=1,761) ⁴⁹⁻⁵⁴	Moderate	Consistent	Imprecise	Undetected	Moderate	Success 49.5% (144/291) vs. 46.6% (89/191) Pooled RR 1.02, 95% CI 0.81 to 1.29, I ² =0% Pain scores (0-100 VAS) Pooled MD -0.66, 95% CI -2.93 to 1.43, I ² =0%

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Pain, Arm pain success ^a Arm pain scores ^b <i>Intermediate term</i>	Success 4 (N=948) ^{45,46,55,56} Pain scores 9 (N=1,741) ^{50,53,55,57,58,60-62,67}	Moderate	Consistent	Imprecise	Undetected	Moderate	Success 61.1% (334/547) vs. 62.6% (251/401) Pooled RR 1.0, 95% CI 0.85 to 1.14, I ² =37.9% Pain scores (0-100 VAS) Pooled MD -1.86, 95% CI -4.03 to -0.56, I ² =0%
Pain, Arm pain success ^a Arm pain scores ^b <i>Long Term</i>	Success 1 (N=232) ⁶³ Pain scores 5 (N=1,195) ^{57,63-66}	Moderate	Unknown (success) Consistent (scores)	Precise	Undetected	Moderate	Success 85.7% (108/126) vs. 75.5% (80/106) RR 1.14, 95% CI 1.0 to 1.29 Pain scores (0-100 VAS) Pooled MD -4.55, 95% CI -7.62 to -1.68, I ² =0%,
Function, Neurologic Neurological Success JOA <i>Short-term</i>	Success 5 (N=1,493) ^{45,46,51,54,56} JOA scores 1 (N=60) ⁶⁸	Moderate	Consistent	Precise	Undetected	Moderate	Success 95.5% (791/828) vs. 90.5% (602/665) Pooled RR 1.05, 95% CI 1.02 to 1.08, I ² =0% JOA scores (0-17) MD 0.25, 95% CI -0.25 to 0.75

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Function, Neurologic Neurological Success JOA Intermediate term	Success 6 (N=1,574) ^{50,53,55,57,61,69} JOA scores 4 (N=354) ^{59,68,70,71} Nurick 1 (N=285) ⁷²	Moderate	Consistent	Precise (success and Nurick) Imprecise (JOA)	Unreported	Moderate	Success 93.3% (835/895) vs. 89.5% (608/679) Pooled RR 1.03 95% CI 1.0 to 1.06, I ² =0% JOA scores (0-17) Pooled MD 0.60, 95% CI -0.007 to 0.97, I ² =1.9% (Highest quality RCT: RR 0.20, 95% CI -1.30 to 1.70) Nurick Grade 99.4% (156/157) vs. 96.9% (124/128) RR 1.03, 95% CI 0.99 to 1.06
Function, Neurologic Neurological Success Long-term	Success 5 (N=1,180) ^{57,63-66}	Moderate	Consistent	Precise	Unreported	Moderate	Success 89.9% (599/666) vs. 86.6% (445/514) Pooled RR 1.02, 95% CI 0.97 to 1.09, I ² =43.3%

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Function, General NDI Success NDI Scores SF-36/12 Success (PCS and MCS) SF-36/12 scores (PCS and MCS) Short-term	NDI Success 6 (N=1,900) ^{45,46,51,54,56,61} NDI Scores 8 (N=2,125) ^{47-51,58,63,72} SF-36/12 Success (PCS) 2 (N=466) ^{45,56} SF-36/12 PCS scores 6 (N=1,779) ^{48,49,51,53,54,73} SF-36/12 Success (MCS) 2 (N=466) ^{45,56} SF-36/12 MCS scores 6 (N=1,779) ^{48,49,51,53,54,73}	Moderate	Consistent	Precise	Unreported	Moderate	NDI Success 85.7% (490/572) vs. 82.3% (348/423) Pooled RR 1.07, 95%CI 1.01 to 1.13, I ² =31.6% NDI scores (0-100) Pooled MD -3.13, 95%CI -4.29 to -1.99, I ² =0% SF-36/12 PCS Success 81.7% (228/279) vs. 75.9% (142/187) Pooled RR 1.08, 95%CI 0.96 to 1.23, I ² =0% SF-36/12 PCS Scores (0-100) Pooled MD 1.67, 95% CI 0.59 to 2.87, I ² =0% SF-36/12 MCS Success 49.1% (137/279) vs. 42.8% (80/187) Pooled RR 1.13 95%CI 0.86 to 1.50, I ² =0% SF-36/12 scores (MCS) (0-100) MD 1.14, 95% CI -0.14 to 2.17, I ² =0%

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Function, General NDI Success NDI Scores SF-36/12 Success (PCS and MCS) SF-36/12 scores (PCS and MCS) Odom's Criteria Intermediate term	NDI Success 6 (N=1,678) ^{50,53,55,57,61,74} NDI Scores 12 (N=2,027) ^{47,48,50,53,55,57-59,61,62,71,75} SF-36/12 Success (PCS) 4 (N=939) ^{45,46,53,55} SF-36/12 PCS scores 7 (N=1,684) ^{48,50,53,55,57,61,64} SF-36/12 Success (MCS) 4 (N=939) ^{45,46,53,55} SF-36/12 scores (MCS) 7 (N=1,684) ^{45,46,53,55} Odom's Criteria 1 (N=682) ^{c72}	Moderate	Consistent	Precise	Undetected	Moderate	NDI Success 82.9% (780/941) vs. 78.2% (576/737) Pooled RR 1.07, 95% CI 1.01 to 1.14, I ² =8.4% NDI scores (0-100) Pooled MD -2.10, 95% CI -3.94 to -0.35, I ² =49.3% SF-36/12 PCS success 73.2% (396/541) vs. 60.6% (241/398) Pooled RR 1.16 95% CI 1.00 to 1.41, I ² =61.2% SF-36/12 PCS scores (0-100) Pooled MD 2.13, 95% CI 0.77 to 3.33, I ² =0% SF-36/12 MCS success 47.3% (256/541) vs. 48.0% (191/398) Pooled RR 0.97 95% CI 0.80 to 1.16, I ² =27.5% SF-36/12 scores (MCS) (0-100) Pooled MD 0.83, 95% CI -0.75 to 2.41, I ² =32.2% Odom's Criteria^c Excellent or Good 45.7% (172/376) vs. 43.1% (132/306), RR 1.06, 95% CI 0.90 to 1.26 Fair: 8.0% (15/188) vs. 9.8% (15/153), RR 0.81, 95% CI 0.41 to 1.61 Poor: 0.5% (1/188) vs. 3.9% (6/153), RR 0.14, 95% CI 0.02 to 1.11

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Function, General NDI Success NDI Scores SF-36/12 Success (PCS and MCS) SF-36/12 scores (PCS and MCS) Long-term	NDI Success 4 (N=1,047) ^{57,63,65,66} NDI Scores 6 (N=1,291) ^{48,57,63-66} SF-36/12 Success (PCS) 1 (N=231) ⁶³ SF-36/12 PCS scores 5 (N=1,191) ^{57,63-66} SF-36/12 success (MCS) 1 (N=231) ⁶³ SF-36/12 MCS scores 3 (N=574) ^{63,64,66}	Moderate	Consistent	Precise	Undetected	Moderate	NDI success 86.4% (513/594) vs.80.8% (366/453) Pooled RR 1.06, 95% CI 0.99 to 1.15, I ² =35.5% NDI scores (0-100) Pooled MD -3.30 95%CI -5.13 to 1.02, I ² =0% SF-36/12 PCS success 72.0% (90/125) vs.74.5% (79/106) RR 0.97, 95%CI 0.83 to 1.13 SF-36/12 PCS scores (0-100) MD 1.76, 95% CI 0.44 to 3.07, I ² =0% SF-36/12 MCS success 47.2% (59/125) vs. ACDF: 43.4% (46/106) RR 1.09, 95% CI 0.82 to 1.45 SF-36/12 MCS scores (0-100) Pooled MD 0.64, 95% CI -1.47 to 2.82, I ² =0%
Quality of Life	No studies	N/A	N/A	N/A	N/A	N/A	N/A

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Reoperation at index level 24 months 36-40 months 60 months >60 months	24 months 9 (N=2,323) ^{53,54,57,61,62,67,74-76} 48 months 3 (N=847) ^{47,70,72,75} 60 months 4 (N=957) ^{55,59,77,78} >60 months 7 (N=1,992) ^{48,55,57,63,64,66,79}	Low	Consistent	Precise	Undetected	High	24 months 2.9% (36/1250) vs. 6.2% (66/1073) Pooled RR 0.49, 95% CI 0.28 to 0.80, I ² =16.2% 48 months 3.6% (18/494) vs. 7.4% (28/380) Pooled RR 0.50, 95% CI 0.22 to 0.98, I ² =0% 60 months 4.9% (27/547) vs. 12.4% (51/410) Pooled RR 0.39, 95% CI 0.15 to 0.71, I ² =37.4% >60 months 5.2% (56/1085) vs. 12.5% (113/907) Pooled RR 0.44, 95% CI 0.29 to 0.60, I ² =0%

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Neurological deficit (variably defined by authors)	<p>24 months (cumulative) 1 (N=463)⁸⁰</p> <p>24-48 months 1 (N=463)⁶¹</p> <p>120 months (cumulative) 1 (N=463)⁷⁹</p> <p>84 months (cumulative) 1 (N=245)⁶⁶</p>	Moderate	Unknown ^d	Imprecise	Undetected	Low	<p>1 RCT 24 months, acute neurologic change^e: 3.3% (8/242) vs. 3.2% (7/221) RR 1.04, 95% CI 0.38 to 2.83</p> <p>24-48 months, severe deficit (WHO grade 3 or 4): 0% (0/242) vs. 1.0% (2/221)</p> <p>120 months, neurological AEs Any: 43.1% (104/242) vs. 43.8% (97/221), RR 0.98, 95% CI 0.80 to 1.21 WHO grade 3 or 4: 4.5% (11/242) vs. 6.9% (15/221), RR 0.67, 95% CI 0.31 to 1.43</p> <p>1 RCT 84 months, neurological failure: 11.4% (19/164) vs. 11.5% (9/81), RR 1.04, 95% CI 0.49 to 2.20</p>
Mortality (all cause)	<p>24 months 3 (N=1,181)^{53,57,76}</p> <p>36 months 2 (N=504)^{52,80}</p> <p>>60 months 2 (N=773)^{57,79}</p>	Moderate	Consistent	Imprecise downgrade 2 for rare event	Undetected	Insufficient	<p>Mortality was uncommon; most deaths do not appear to be procedure related.</p> <p>24 months (N range, 260–532) Range: 0%–0.4% vs. 0%–1.3%</p> <p>36 months (Ns, 463 and 41) Range: 0%–5.0% vs. 0%–0.5% (0% to 0.5% in larger trial)</p> <p>>60 months (Ns, 232 and 541) Range: 0.9%–1.4% vs. 2.2%–2.4%</p> <p>Individual studies may have been underpowered to detect rare events, particularly procedure-specific events</p>

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Serious AEs (any, cumulative)	<p>24 months 5 (N=1,611)^{53,72,74,76,80}</p> <p>48 months 2 (N=723)^{61,73}</p> <p>60 months 1 (N=304)⁵⁵</p> <p>>60 months 2 (N=614)^{63,79}</p>	Moderate	Unknown ^f	Imprecise	Undetected	Low	<p>24 months 24.6% (216/878) vs. 30.6% (224/733) Pooled RR 0.83, 95% CI 0.64 to 0.97, I²=24.6%</p> <p>48 months 32.1% (135/421) vs. 41.1% (124/302) Pooled RR 0.93, 95% CI 0.71 to 1.24, I²=0%</p> <p>60 months 21.0% (45/214) vs. 17.4% (33/190) RR 1.21, 95% CI 0.81 to 1.81</p> <p>>60 months 48.1% (176/366) vs. 56.9% (141/248) Pooled RR 0.90, 95% CI 0.73 to 1.06, I²=0%</p>

ACDF=anterior cervical discectomy and fusion; AE=adverse events; C-ADR=cervical artificial disc replacement; CI=confidence interval; MCS=Mental Component Score; MD=mean difference; mJOA=modified Japanese Orthopaedic Association score; NDI=Neck Disability Index; PCS=Physical Component Score; RCT=randomized controlled trial; RR=risk ratio; SF-36/12=36- or 12-Item Short Form Health Survey; SSED=Summary of Safety and Effectiveness Data (FDA); VAS=visual analog scale; WHO=World Health Organization.

^a Some studies reported arm pain success in both arms. We used the lower risk ratio reported for the conservative analysis.

^b Some studies reported arm pain success in both arms. We the smaller difference reported for the conservative analysis.

^c Based on the largest, highest quality trial.

^d Categorization, types of conditions included, and definitions were not well described in studies various general terms were used (e.g., new deficit, neurological failure, neurological AE).

^e Sensory upper extremity and lower extremity, motor upper extremity, myelopathy, and SCI.

^f Definitions of serious adverse events varied across RCTs; many RCTs included events that may not be attributed to the devices/procedures.

Table G-10. Key Question 8: C-ADR versus ACDF strength of evidence – 2-level interventions

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Pain, Neck pain success Neck pain scores <i>Short-term</i>	Success 2 (N=692) ^{81,82} Pain scores 3 (N=764) ⁸³⁻⁸⁵	Moderate	Consistent	Precise (success) Imprecise (scores)	Undetected	Moderate	Success 88.2% (372/422) vs. ACDF: 80.7% (218/270) Pooled RR 1.10, 95% CI 1.01 to 1.23, I ² =0.8% Pain scores (0-100 VAS) Pooled MD -5.83, 95% CI -12.28 to 0.61, I ² =50.3%)
Pain, Neck pain success Neck pain scores <i>Intermediate term</i>	Success 2 (N=678) ^{81,82} Pain scores 4 (N=707) ^{68,83,85,86}	Moderate	Consistent	Precise (success) Imprecise (scores)	Undetected	Moderate	Success 86.9% (365/420) vs. ACDF: 83.3% (215/258) Pooled RR 1.06, 95% CI 0.98 to 1.15, I ² =0% Pain scores (0-100 VAS) Pooled MD -8.21, 95% CI -13.83 to -4.25, I ² =23%
Pain, Neck pain success Neck pain scores <i>Long Term</i>	Success 1 (N=221) ⁸² Pain scores 3 (N=615) ^{66,85,86}	Moderate	Consistent	Precise (success) Imprecise (scores)	Undetected	Moderate	Success 91.2% (114/125) vs. ACDF: 81.3% (78/96) RR 1.12, 95% CI 1.01 to 1.25 Pain scores (0-100 VAS) Pooled MD -8.13, 95% CI -15.18 to -2.97, I ² =55.9%
Pain, Arm pain success ^a Arm pain scores ^b <i>Short-term</i>	Success 2 (N=692) ^{81,82} Pain scores 2 (N=692) ^{81,82}	Moderate	Consistent	Precise (success) Imprecise (scores)	Undetected	Moderate	Success 70.6% (298/422) vs. 74.1% (200/270) Pooled RR, 1.00, 95% CI 0.90 to 1.14, I ² =0% Pain scores (0-100 VAS) Pooled MD -3.72, 95% CI -9.53 to 1.62, I ² =0%

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Pain, Arm pain success ^a Arm pain scores ^b <i>Intermediate term</i>	Success 2 (N=678) ^{81,82} Pain scores 3 (N=627) ^{68,83,86}	Moderate	Consistent	Precise (success) Imprecise (scores)	Undetected	Moderate	Success 71.9% (302/420) vs. 74.0% (191/258) Pooled RR, 1.02, 95% CI 0.92 to 1.14, I ² =0% Pain scores (0-100 VAS) Pooled MD -9.95, 95% CI -15.10 to -5.15, I ² =0%
Pain, Arm pain success ^a Arm pain scores ^b <i>Long term</i>	Success 1 (N=220) ⁸² Pain scores 2 (N=535) ^{66,86}	Moderate	Consistent	Precise (success) Imprecise (scores)	Undetected	Moderate	Success 82.3% (102/124) vs. 87.5% (84/96) RR, 0.94, 95%CI 0.84 to 1.05 Pain scores (0-100 VAS) Pooled MD -5.08, 95% CI -11.73 to 1.70, I ² =1.4%
Function, Neurologic Neurological Success JOA <i>Short-term</i>	Success 2 (N=692) ^{81,82} JOA 1 (N=96) ⁸⁵	Moderate	Consistent	Precise (success) Imprecise (JOA)	Undetected	Moderate	Success C-ADR: 91.0% (382/420) vs. ACDF: 87.9% (239/272) Pooled RR 1.03, 95% CI 0.96 to 1.10, I ² =0% Mean JOA (0-17 scale) 15.2 vs. 14.9, p>0.05
Function, Neurologic Neurological Success JOA <i>Intermediate term</i>	Success 2 (N=604) ^{83,86} JOA 1 (N=96) ⁸⁵	Moderate	Consistent	Precise (success) Imprecise (JOA)	Undetected	Moderate	Success 91.4% (339/371) vs. ACDF: 90.6% (211/233) Pooled RR 0.99, 95% CI 0.93 to 1.07, I ² =0% Mean JOA (0-17 scale) 15.4 vs. 15.3, p>0.05
Function, Neurologic Neurological Success JOA <i>Long term</i>	Success 2 (N=535) ^{66,86} JOA 1 (N=96) ⁸⁵	Moderate	Consistent	Precise (success) Imprecise (JOA)	Undetected	Moderate	Success 93.2% (315/338) vs. ACDF: 84.8% (167/197) Pooled RR 1.10, 95% CI 1.01 to 1.20 I ² =0% Mean JOA (0-17 scale) 15.4 vs. 15.2, p>0.05

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Function, General NDI Success NDI Scores SF-36/12 Success (PCS and MCS) SF-36/12 scores (PCS and MCS) Short-term	NDI Success 2 (N=692) ^{83,84} NDI Scores 3 (N=772) ⁸³⁻⁸⁵ SF-36/12 Success (PCS) 2 (N=657) ^{81,82} SF-36/12 scores (PCS) 2 (N=692) ^{83,84} SF-36/12 Success (MCS) 2 (N=657) ^{81,82} SF-36/12 scores (MCS) 1 (N=380) ⁸⁴	Moderate	Consistent	Precise (success) Imprecise (scores)	Undetected	Moderate	NDI success 89.3% (377/422) vs. 80.0% (216/270) Pooled RR 1.12, 95% CI 1.04 to 1.22, I2=0% NDI scores Pooled MD -5.79, 95% CI -8.44 to -3.21, I2=0% SF-36/12 success (PCS) 76.5% (303/396) vs. 69.3% (181/261) Pooled RR 1.11, 95% CI 0.88 to 1.46 I2=72.7% SF-36/12 scores (PCS) (0-100) Pooled MD 3.29, 95% CI 0.63 to 6.19, I2=36.6% SF-36/12 success (MCS) 50.3% (199/396) vs. 45.2% (118/261) Pooled RR 1.08, 95% CI 0.82 to 1.41, I2=43.9% SF-36/12 scores (MCS) (0-100) MD 1.00 95% CI -1.37 to 3.37

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Function, General NDI Success NDI Scores SF-36/12 Success (PCS and MCS) SF-36/12 scores (PCS and MCS) Odom's Criteria Intermediate term	NDI success 1 (N=307) ⁸⁶ NDI scores 4 (N=707) ^{68,83,85,86} SF-36/12 success (PCS) 2 (N=639) ^{81,84} SF-36/12 scores (PCS) 3 (N=627) ^{68,83,86} SF-36/12 scores (MCS) 2 (N=639) ^{81,84} SF-36/12 scores (MCS) 2 (N=665) ^{84,87} Odom's Criteria 1 RCT (N=62) ⁶⁸	Moderate	Consistent	Precise (success) Imprecise (scores)	Undetected	Moderate	NDI success 89.2% (149/167) vs. 77.9% (109/140) RR 1.15, 95% CI 1.03 to 1.27 NDI scores (0-100) Pooled MD -7.69, 95% CI -10.30 to -5.10, I ² =0% SF-36/12 success (PCS) 83.7% (335/400) vs. 79.1% (189/239) Pooled RR 1.06, 95% CI 0.92 to 1.36 I ² =69.7% SF-36/12 scores (PCS) (0-100) Pooled MD 4.80, 95% CI 2.74 to 6.87, I ² =0% SF-36/12 Success (MCS) 62.3% (249/400) vs. 65.3% (156/239) Pooled RR 0.98, 95% CI 0.85 to 1.18, I ² =0% SF-36/12 scores (MCS) (0-100) Pooled MD 1.12, 95% CI -1.07 to 3.29, I ² =0% Odom's Criteria 96.7% vs. 84.4%, RR 1.15, 95% CI 0.97 to 1.34

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACRF
Function, General NDI Success NDI Scores SF-36/12 Success (PCS) SF-36/12 scores (MCS) Long term	NDI success 2 (N=535) ^{66,86} NDI scores 3 (N=615) ^{66,85,86} SF-36/12 success (PCS) 1 (N=216) ⁸² SF-36/12 scores (PCS) 2 (N=535) ^{66,86} SF-36/12 success (MCS) 1 (N=216) ⁸² SF-36/12 scores (MCS) 1 (N=269) ⁶⁶	Moderate	Consistent	Precise (success) Imprecise (scores)	Undetected	Moderate	NDI success 84.3% (285/338) vs. 73.6% (145/197) Pooled RR 1.16, 95% CI 1.04 to 1.30, I ² =0% NDI scores (0-100) Pooled MD -7.63, 95% CI -10.64 to -4.52, I ² =0% SF-36/12 success (PCS) 76.4% (94/123) vs. 71.0% (66/93) RR 1.08 95% CI 0.91 vs. 1.27 SF-36/12 scores (PCS) (0-100) Pooled MD 2.32, 95% CI -0.03 to 4.71, I ² =0% SF-36/12 success (MCS) 53.7% (66/123) vs. 52.7% (49/93), RR 1.02, 95% CI 0.79 to 1.31 SF-36/12 scores (MCS) (0-100) MD 2.90, 95% CI -0.25 to 6.05
Quality of Life	No studies	NA	NA	NA	NA	NA	NA

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Reoperation at index level 24 months 36 to 48 months 60 months >60 months	24 months 2 (N=727) ^{84,88} 36 to 48 months 1 (N=330) ⁸⁷ 60 months 1 (N=339) ⁷⁸ >60 months 2 (N=727) ^{66,86}	Moderate	Consistent	Imprecise	Undetected	Low	24 months 2.8% (12/434) vs. 9.2% (27/293) Pooled RR 0.28, 95% CI 0.13 to 0.61, I ² =0% 36 to 48 months 4.0% (9/225) vs. 15.2% (16/105) RR 0.26, 95% CI 0.12 to 0.57 60 months 4.7% (11/234) vs. 18.1% (19/105) RR 0.26, 95% CI 0.13 to 0.53 >60 months 4.4% (19/434) vs. 15.0% (44/293) Pooled RR 0.29, 95% CI 0.16 to 0.52, I ² =0%
Neurological deficit or events	24 months 1 (N=65) ⁶⁸ 48 months 1 (N=330) ⁸⁷ 84 months 1 (N=330) ⁸⁷	Moderate	Unknown (various definitions)	Imprecise	Undetected	Insufficient	24 months 0% (0/31) vs. 0% (0/34) 48 months 6.2% (14/225) vs. 7.6% (8/105) RR 0.82, 95% CI 0.35 to 1.89 84 months 6.4% (14/225) vs. 17.1% (18/105) RR 0.36, 95% CI 0.19 to 0.70
Mortality (all cause, cumulative)	1 (N=397) ⁸⁴	Moderate	Unknown	Imprecise (Downgrade 2 for rare event)	Undetected	Insufficient	1.0% (2/209) vs. 1.6% (3/188) RR 0.60, 95% CI 0.10 to 3.55 Individual studies may have been underpowered to detect rare events, particularly procedure-specific events

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Serious AEs ^c	24 months 2 (N=727) ^{84,86-89} 120 months 1 (N=397) ⁸⁶	Moderate	Unknown	Imprecise	Undetected	Low	24 months 29.3% (127/434) vs. 42.3% (124/293) Pooled RR 0.73, 95% CI 0.58 to 0.93, I ² =0% 120 months 66.7% (124/209) vs. 70.9% (120/188) RR 0.93, 95% CI 0.80 to 1.09

ACDF=anterior cervical discectomy and fusion; AE=adverse events; C-ADR=cervical artificial disc replacement; CI=confidence interval; MCS=Mental Component Score; MD=mean difference; mJOA=modified Japanese Orthopaedic Association score; NA = not applicable; NDI=Neck Disability Index; PCS=Physical Component Score; RCT=randomized controlled trial; RR=risk ratio; SF-36/12=36- or 12-Item Short Form Health Survey; SSED=Summary of Safety and Effectiveness Data (FDA); VAS=visual analog scale.

^a Some studies reported arm pain success in both arms. We used the lower risk ratio reported for the conservative analysis.

^b Some studies reported arm pain success in both arms. We the smaller difference reported for the conservative analysis.

^c Serious adverse events were variably defined across studies and included broad range of events that may not be linked with either procedure; see full report.

Table G-11. Key Question 8: C-ADR versus ACDF strength of evidence – mixed level (i.e., 1, 2, or 3) interventions

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Pain, Neck pain scores <i>Intermediate term</i>	1 (N=50) ⁹⁰	Moderate	Unknown	Imprecise	Undetected	Low	60 months VAS neck pain (0-10) , median (IQR): 3.6 (3.2 to 4.1) vs. 3.9 (3.0 to 4.4), p=0.203
Function, Neurologic JOA <i>Intermediate term</i>	1 (N=81) ⁹¹	Moderate	Unknown	Imprecise	Undetected	Insufficient	36 months JOA score (0-17 scale) , mean (estimated from graph): 15.4 vs. 14.7, p=0.016
Function, General NDI scores SF-36 PCS scores Odom's Criteria <i>Intermediate term</i>	NDI scores 2 (N=133) ^{90,91} SF-36 PCS, Odom's Criteria 1 (N=51) ⁹¹	Moderate	Unknown	Imprecise	Undetected	Insufficient	NDI scores (0-50 scale) 1 RCT, 36 months: Mean 12 vs. 18 (estimated from graph), p<0.001 1 RCT, 60 months: Median 7 (IQR 6 to 8) for both groups SF-36 PCS scores (0-100) , 1 RCT, 36 months: Mean 50.5 vs. 44.5 (estimated from graph), p<0.05 Odom's Criteria , 1 RCT, 36 months: Excellent: 58.5% (24/41) vs. 58.5% (23/40), RR 1.02, 95% CI 0.70 to 1.47 Good: 34.1% (14/41) vs. 25% (10/40), RR 1.37, 95% CI 0.69 to 2.71
Quality of Life	No studies	NA	NA	NA	NA	NA	NA
Reoperations at index level	2 (N=136) ^{91,92}	High	Unknown	Imprecise	Undetected	Insufficient	12–36 months, 1 RCT (N=53): 4% (1/25) vs. 7.1% (2/28), RR 0.56, 95% CI 0.05 to 5.81 36 months, 1 RCT (N=83): none in either group

Outcome Timing	Number of RCTs (Patients) Author Year	Study Limitations	Consistency	Precision	Reporting Bias	Strength of Evidence	Findings, Direction, and Magnitude of Effect C-ADR Vs. ACDF
Neurologic deficit	2 (N=136) ^{91,92}	High	Unknown	Imprecise	Undetected	Insufficient	1 RCT: Transient recurrent nerve paralysis, 4% (1/25) vs. 3.6% (1/28), RR 1.12, 95% CI 0.07 to 16.98 Worsening arm pain and neurological deficit, 0% (0/25) vs. 3.6% (1/28) 1 RCT (N=83): No intraoperative neurologic complications in either group
Mortality	1 (N=83) ⁹¹	Moderate	Unknown	Imprecise (Downgrade 2 for rare event)	Undetected	Insufficient	No deaths occurred in either group through 90 months.
Serious AEs	2 (N=136) ^{91,92}	High	Unknown	Imprecise	Undetected	Insufficient	1 RCT DVT: 2.4% (1/41) vs. 0% (0/42) HO (severity NR): 2.4% (1/41) vs. N/A CSF leak and wound hematoma: no cases in either group 1 RCT Wound hematoma, required urgent evacuation: 0% (0/25) vs. 3.6% (1/28) Recurrent cervical pain, required local infiltration (3–6 months): 0% (0/25) vs. 10.7% (3/28)

ACDF=anterior cervical discectomy and fusion; AE=adverse events; C-ADR=cervical artificial disc replacement; CI=confidence interval; CSF=cerebrospinal fluid; DVT=deep vein thrombosis; HO=heterotopic ossification; JOA=Japanese Orthopaedic Association score; MD=mean difference; NA=not applicable; NDI=Neck Disability Index; PCS=Physical Component Score; RCT=randomized controlled trial; RR=risk ratio; SF-36=Short-form 36 questionnaire; VAS=visual analog scale.

Table G-12. Key Question 9: Interbody graft material or device – standalone cage versus plate and cage

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Fusion	8 RCTs (N=515) ⁹³⁻¹⁰⁰	Moderate	Consistent	Direct	Precise	Undetected	12 months: RR 0.99, 95% CI 0.92 to 1.06 24 months: RR 1.00, 95% CI 0.93 to 1.08 36 months: RR 1.00, 95% CI 0.97 to 1.03	Moderate
Neck or nonspecific pain VAS	4 RCTs (N=230) ^{96,97,99,101}	Moderate	Inconsistent	Direct	Imprecise	Undetected	<3 months: MD -0.90, 95% CI -1.29 to 0.73 3 months: MD 0.20, 95% CI -0.35 to 0.75 6 months: MD 0.64, 95% CI -0.66 to 2.17 12 months: MD 0.30, 95% CI -0.54 to 1.43 24 months: MD -0.20, 95% CI -0.63 to 0.23	Insufficient
Arm pain VAS	4 RCTs (N=186) ^{96,97,99,101}	Moderate	Consistent	Direct	Imprecise	Undetected	<3 months: MD -0.24, 95% CI -1.55 to 1.12 3 months: MD 0.06, 95% CI -0.57 to 0.58 6 months: MD -0.15, 95% CI -0.56 to 0.14 12 months: MD -0.11, 95% CI -0.55 to 0.29 24 months: MD 0.20, 95% CI -0.09 to 0.49	Low
Neurologic Function JOA scores	5 RCTs (N=424) ^{93-95,100,101}	Moderate	Consistent	Direct	Imprecise	Undetected	<3 months: MD 2.63, 95% CI -3.86 to 9.29 3 months: MD 0.00, 95% CI -1.70 to 1.70 6 months: MD -0.08, 95% CI -0.70 to 0.59 12 months: MD -0.08, 95% CI -0.56 to 0.46 24 months: MD 0.00, 95% CI -0.69 to 0.69 36 months: MD -0.13, 95% CI -1.03 to 0.81)	Low

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
General Function NDI scores Neck Pain Disability Index (German) Odom Criteria	6 RCTs (N=472) ^{93,94,97,99-101} 1 RCT (N=41) ⁹⁸ 3 RCTs (N=202) ^{96,98,100}	Moderate	Consistent	Direct	Imprecise	Undetected	<3 months: MD -5.39, 95% CI -9.91 to 5.19 3 months: MD -0.14, 95% CI -3.14 to 2.16 6 months: MD -0.08, 95% CI -3.25 to 4.70 12 months: MD -0.13, 95% CI -2.31 to 1.59 24 months: MD -0.13, 95% CI -2.41 to 2.04 36 months: MD 0.15, 95% CI -2.73 to 2.88 Endpoint scores at 24 months: 25.8% vs. 22.2% Trials reported no differences between treatments on ratings of excellent, good, fair and bad; or between excellent+good and fair+poor; or a mean score (1-4 scale)	Low
Quality of Life Various	5 RCTs (N=253) ^{93,95,97-99}	Moderate	Consistent	Direct	Imprecise	Undetected	There were no differences at longer followups (beyond 3 months) on the SWAL-QOL questionnaire, the Eating Assessment Tool, or dysphagia ratings. No study reported a return to the operating for dysphagia. There were no differences on the Voice Handicap Index in one trial.	Low
Adverse Event: Adjacent-level ossification	3 RCTs (N=239) ^{93,96,100}	Moderate	Consistent	Direct	Precise	Undetected	8% vs. 27%, RR 0.25, 95% CI 0.12 to 0.52 ALO severity favored standalone cage in 1 trial (0.208 vs. 0.818, p=0.001)	Low
Adverse Event: Subsidence	1 RCT (N=46) ⁹⁶	Moderate	Unknown	Direct	Imprecise	Undetected	12 months: 12.5% vs. 9.1%, RR 1.38, 95% CI 0.25 to 7.48 24 months: 16.7% vs. 13.6%, RR 1.22, 95% CI 0.31 to 4.87	Insufficient

ALO=adjacent level ossification; CI=confidence interval; JOA=Japanese Orthopedic Association; MD=mean difference; NDI=Neck Disability Index; RCT=randomized controlled trial; RR=relative risk; VAS=Visual Analogue Scale

Table G-13. Key Question 9: Interbody graft material or device – titanium cage/titanium-coated PEEK cage versus PEEK cage

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Fusion	3 RCTs (N=217) ¹⁰²⁻¹⁰⁴	Moderate	Consistent	Direct	Imprecise	Undetected	1 trial at 99.7 months: 60/60 patients achieved 3-level fusion 1 trial at 24 months: 32/27 (86.5%) levels fused vs. 34/34 (100%) levels, p=0.0335 1 trial at 12 months: 26/59 (44.1%) levels completely fused vs. 75/85 (88.2%) levels completely fused (p<0.001)	Low
Neurologic Function	1 RCT (N=60) ¹⁰²	Moderate	Unknown	Direct	Imprecise	Undetected	Endpoint difference favored PEEK: -1.4, 95% CI -2.33 to -0.47	Insufficient
General Function	2 RCT (N=113) ^{102,104}	Moderate	Consistent	Direct	Imprecise	Undetected	Odom Criteria: 1 trial (p<0.05): Excellent: 24% vs. 35% Good: 31% vs. 39% Fair: 28% vs. 16% Bad: 17% vs. 10% 1 trial: Excellent: 21% vs. 28% Good: 54% vs. 52% Fair: 14% vs. 8% Poor: 11% vs. 12% Success: 75% vs. 80%, p=0.6642	Low
NDI	1 RCT (N=60) ¹⁰²						NDI: Endpoint difference favors PEEK: 6.4, 95% CI 5.13 to 7.67	
Quality of Life	No studies	NA	NA	NA	NA	NA	NA	NA
Adverse Events: Subsidence	3 RCTs (N=217) ¹⁰²⁻¹⁰⁴	Moderate	Inconsistent	Direct	Imprecise	Undetected	1 trial (N=104, 166 levels): 20.6% vs. 21.4%, p=0.875 1 trial (N=60, 180 levels): 34.5% vs. 5.4%, p<0.05 1 trial (N=53, 71 levels): 16.2% vs. 0%, p<0.001	Insufficient

CI=confidence interval; NA=not applicable; NDI=Neck Disability Index; PEEK=polyetheretherketone; RCT=randomized controlled trial

Table G-14. Key Question 9: Interbody graft material or device – autograft, allograft, other osteogenic materials

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Fusion	6 RCTs (N=534) ¹⁰⁵⁻¹¹⁰	Moderate	Unknown	Direct	Imprecise	Undetected	<p>1 trial (N=244) i-FACTOR vs. Local graft: 97.30% vs. 94.44%, p=0.2513</p> <p>1 trial (N=20) BMP-2 vs. ICBG: 100% vs. 100%, p=1.0</p> <p>1 trial (N=100) Biphasic calcium phosphate ceramic vs. ICBG: 100% vs. 100%, p=1.0</p> <p>1 trial (N=27) Allograft vs. Local graft: 100% vs. 100%, p=1.0 Fusion grade: (p=0.73) F: 23.2% vs. 28.6% F+: 38.4% vs. 42.8% F++: 38.4% vs. 28.6%</p> <p>1 trial (N=66) Calcium sulphate + demineralized bone matrix vs. Iliac cancellous bone, 12 mos 104 levels, 24 mos levels NR: 12 months: 94.3% vs. 100%, p=NR 24 months: 100% vs. 100%, p=1.0</p> <p>1 trial (N=77) Hydroxyapatite + demineralized bone matrix vs. B-tricalcium phosphate + hydroxyapatite: X-ray: 87% vs. 87%, p=1.0 CT: 87% vs. 72%, p=0.16</p>	Insufficient for all comparisons

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Neck Pain VAS NRS NPRS	5 RCTs (N=440) ^{105,106,108-110}	Moderate	Unknown	Direct	Imprecise	Undetected	<p>1 trial (N=244) i-FACTOR vs. Local graft, VAS endpoint: 1.79, 95% CI 1.33 to 2.24 vs. 2.25, 95% CI 1.78 to 2.72, p=0.4619</p> <p>1 trial (N=26) BMP-2 vs. ICBG: 20-point NRS: MD 13.0 vs. MD 9.0, p>0.05</p> <p>1 trial (N=27) Allograft vs. Local graft, 0-10 NPRS: MD -5.09 vs. MD -6.15, p<0.05</p> <p>1 trial (N=64) Calcium sulphate + demineralized bone matrix vs. Local graft, Improved VAS neck pain: 69% vs. 68%, p>0.05</p> <p>1 trial (N=77) Hydroxyapatite + demineralized bone matrix vs. B-tricalcium phosphate + hydroxyapatite, VAS: MD -1.6 vs. -1.8, p=0.82</p>	Insufficient for all comparisons
Arm Pain VAS NRS NPRS	5 RCTs (N=440) ^{105,106,108-110}	Moderate	Unknown	Direct	Imprecise	Undetected	<p>1 trial (N=244) i-FACTOR vs. Local graft, VAS endpoint: 1.56, 95% CI 1.06 to 2.05 vs. 1.95, 95% CI 1.51 to 2.39, p=0.0306</p> <p>1 trial (N=26) BMP-2 vs. ICBG: 20-point NRS: MD -14.0 vs. -8.5, p<0.03</p> <p>1 trial (N=27) Allograft vs. Local graft, 0-10 NPRS: MD -4.55 vs/ -7.24, p<0.05</p> <p>1 trial (N=64) Calcium sulphate + demineralized bone matrix vs. Local graft, Improved VAS neck pain: 70% vs. 68%, p>0.05</p> <p>1 trial (N=77) Hydroxyapatite + demineralized bone matrix vs. B-tricalcium phosphate + hydroxyapatite, VAS: MD -4.2 vs. -3.6, p=0.27</p>	Insufficient for all comparisons

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Neurologic Function Neurologic success JOA	4 RCTs (N=436) ^{105, 107, 109}	Moderate	Unknown	Direct	Imprecise	Undetected	1 trial (N=244) i-FACTOR vs. Local graft, Neurologic success: 94.87% vs. 93.70%, p=0.6944 1 trial (N=26) BMP-2 vs. ICBG: Neurologic success: 100% vs. 100%, p=1.0 1 trial (N=100) Biphasic calcium phosphate ceramic vs. ICBG, JOA score: MD 2.84 vs. 2.48, p=0.17 JOA recovery rate: 86.51% vs. 83.48%, p=0.22 1 trial (N=66) Calcium sulphate + demineralized bone matrix vs. Iliac cancellous bone, JOA score: MD 3.62 vs. 3.22, p>0.05	Insufficient for all comparisons

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
General Function NDI SF-36 2-item SF-12	4 RCTs (N=374) ^{105,106,108,110}	Moderate	Unknown	Direct	Imprecise	Undetected	<p>1 trial (N=244) i-FACTOR vs. Local graft, NDI endpoint: 22.33, 95% CI 18.90 to 25.76 vs. 25.66, 95% CI 22.55 to 28.78, p=0.5607</p> <p>1 trial (N=26) BMP-2 vs. ICBG: NDI improvement from preoperative scores: 52.7 vs. 36.9, p<0.03</p> <p>1 trial (N=27) Allograft vs. Local graft, NDI: MD 41.4 vs. MD 56.5, p<0.05</p> <p>1 trial (N=77) Hydroxyapatite + demineralized bone matrix vs. B-tricalcium phosphate + hydroxyapatite, NDI: MD 22 vs. MD 20, p=0.62</p> <p>1 trial (N=244) i-FACTOR vs. Local graft, SF-36 PCS endpoint: 45.40, 95% CI 43.60 to 47.20 vs. 44.47, 95% CI 42.70 to 46.24, p=0.6461 SF-36 MCS endpoint: 48.43, 95% CI 46.43 to 50.44 vs. 48.41, 95% CI 46.42 to 50.40, p=0.9040</p> <p>1 trial (N=26) BMP-2 vs. ICBG: SF-36 PCS: MD 16.7 vs. MD 14.7, p>0.05 SF-36 MCS: MD 21.8 vs. MD 7.2, p>0.05</p> <p>1 trial (N=27) Allograft vs. Local graft, 2-item SF-12: MD 48.7 vs. MD 65.9, p<0.05</p>	Insufficient for all comparisons
Adverse Events: Adjacent level degeneration	1 RCT (N=319) ¹⁰⁵	Moderate	Unknown	Direct	Imprecise	Undetected	iFACTOR vs. Local graft (N=319): Adjacent segment degeneration: 13.04% vs. 16.45%, p=0.4274	Insufficient

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Adverse Events: Complications	1 RCT (N=33) ¹⁰⁶ 2 NRSI (N=944) ^{111,112}	Moderate	Consistent	Direct	Imprecise	Detected in RCT (Reported harms as “No device-related adverse events”)	BMP-2 vs. No BMP-2 (ICBG, cortical allograft, no BMP-2): 1 RCT (N=33), Additional cervical spine surgery: 5.6% vs. 0%, p>0.05 1 NRSI (N=710), Heterotopic ossification: 78.6% vs. 59.2%, p<0.001 1 NRSI (N=234), Neck Swelling Complications (e.g., delay in discharge, severe dysphagia, reintubation, PEG placement, incision and drainage of surgical site, readmission for swelling): 27.5% vs. 3.6%, p<0.001	Low
Adverse Events: Worse Neurologic Status	1 RCT (N=319) ¹⁰⁵	Moderate	Unknown	Direct	Imprecise	Undetected	iFACTOR vs. Local graft, New intractable neck pain: 44.72% vs. 42.11%, p=0.1149 New radiculopathy: 13.66% vs. 25.00%, p=0.0142 Progression of myelopathy: 0.62% vs. 0%, p=1.0	Insufficient
Adverse Events: Additional surgery	1 RCT (N=319) ¹⁰⁵	Moderate	Unknown	Direct	Imprecise	Undetected	iFACTOR vs. Local graft, Additional cervical spine surgery: 7.45% vs. 10.53%, p=0.34	Insufficient

BMP=bone morphogenic protein; CI=confidence interval; CT=computed tomography; ICBG=iliac crest bone graft; JOA=Japanese Orthopedic Association; MD=mean difference; NDI=Neck Disability Index; N(P)RS=Numeric (Pain) Rating Scale; NRSI=non-randomized studies of interventions; RCT=randomized controlled trial; VAS=Visual Analogue Scale

Table G-15. Key Question 11: Prognostic utility of MRI findings

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Diagnostic accuracy: Presence/longitudinal extent of signal changes	1 systematic review (including 12 observational studies; n=531) ¹¹³ 4 NRSI (n=309) ¹¹⁴⁻¹¹⁷	Medium	Inconsistent	Indirect	Imprecise	Not detected	Seven studies reported significant associations between presence/longitudinal extent of signal changes and poorer functional outcomes, while four studies reported absence of signal changes associated with better outcomes and five studies reported no association with functional outcomes.	Low
Diagnostic accuracy: qualitative T2-weighted signal changes	1 systematic review (including 10 observational studies; n=731) ¹¹³ 6 NRSI (n=848) ^{115,118-122}	Medium	Consistent	Indirect	Imprecise	Not detected	Eleven studies found qualitative T2-weighted signal changes to be associated with functional outcomes measured using JOA or NDI; absence of T2-weighted qualitative signal changes was associated with better outcomes in two studies. Qualitative intensity was not associated with functional outcomes in three studies.	Low
Diagnostic accuracy: signal intensity ratio	1 systematic review (including 1 observational study; n=73) ¹¹³ 3 NRSI (n=368) ¹²³⁻¹²⁵	Medium	Consistent	Indirect	Imprecise	Not detected	Three studies found higher SIR associated with JOA recovery (p<0.001, p=0.006, and p<0.001; AUC 78.6%-84.4%), while one study found no association with T2-weighted SIR while lower T1-weighted SIR was associated with poorer recovery (JOA recovery 48% vs. 19% vs. 60.7%; T1- and T2-weighted ISI changes vs. T2-weighted ISI change only, p=0.0259).	Low
Diagnostic accuracy: segmental abnormalities	1 systematic review (including 2 observational studies; n=208) ¹¹³ 2 NRSI (n=982) ¹²⁶⁻¹²⁸	Medium	Inconsistent	Indirect	Imprecise	Not detected	Snake-eye appearance on axial T2-weighted MRI, ISI in gray and white matter, and endplate abnormalities associated with poorer functional outcomes in one study each, while modic changes were not associated with functional outcomes in one study.	Insufficient

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Diagnostic accuracy: diffusion tensor tractography grading	2 NRSI (n=177) ^{129,130}	Medium	Inconsistent	Indirect	Imprecise	Not detected	Diffusion tensor tractography grading was correlated with JOA scores (r=-0.813; p<0.001) and JOA recovery rates (r=-0.429; p<0.001) in one study; another study found no DTI metrics associated with treatment outcomes	Insufficient
Diagnostic accuracy: diffusion-based spectrum imaging	1 NRSI (n=100) ^{130,131}	Medium	Unknown consistency	Indirect	Imprecise	Not detected	Diffusion-based spectrum imaging features were associated with treatment outcomes; accuracy for predicting mJOA scores was 78.6% (AUC 75.3%), while accuracy for predicting NDI was 64.3% (AUC 54.6%)	Insufficient
Diagnostic accuracy: radiomics-based extra tree model	1 NRSI (n=302) ¹³²	Medium	Unknown consistency	Indirect	Imprecise	Not detected	Radiomics-based extra tree modeling had superior accuracy compared to radiological or clinical-radiological modeling (Accuracy 71%, AUC 75%)	Insufficient

AUC=area under the curve; ISI=increased signal intensity; JOA=Japanese Orthopaedic Association score; MRI=magnetic resonance imaging; NDI=Neck Disability Index; NRSI=nonrandomized studies of intervention; RCT=randomized controlled trial; SIR=signal intensity ratio

Table G-16. Key Question 12: Diagnostic accuracy of imaging assessment

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Diagnostic Accuracy: Predicting Pseudarthrosis	1 retrospective cohort (N=597) ¹³³	Moderate	Unknown	Indirect	Precise	Undetected	Dynamic radiographs were highly sensitive (89.7%; 95% CI 0.758 to 0.971) and moderately specific (81%; 95% CI 0.786 to 0.835) in predicting symptomatic pseudarthrosis in patients requiring revision surgery, with intraoperative documentation of pseudarthrosis as the index and interspinous motion <1 mm as the cutoff.	Low
	1 retrospective cohort (N=125) ¹³⁴	Moderate	Unknown	Indirect	Precise	Undetected	Dynamic radiographs and CT scans had similar accuracy in identifying pseudarthrosis in patients undergoing revision surgery for pseudarthrosis or ASD pathology (sensitivity, 86.3% [95% CI, 81.6 to 91] vs. 87.2% [83.2 to 91.3]; specificity, 96.1% [93.4 to 98.8] vs. 97.4% [95.5 to 99.3]),, with surgical exploration of fusion as the index and interspinous motion ≥1 mm and superadjacent interspinous motion ≥4 mm as the cutoff.	Low
	1 retrospective cohort (N=143; 36 analyzed) ¹³⁵	High	Unknown	Indirect	Precise	Undetected	In dynamic radiographs, suspected pseudarthrosis rates were lower using angular versus linear methods (N=143; 18.5% [45/242 levels] vs. 28% [68/242 levels], p=NR). In 1-year validation CTs (n=36; 66 levels), pseudarthrosis was identified in 13 patients (13 levels), of whom 5 underwent revision surgery; use of the angle method resulted in similar sensitivity (85%) but higher specificity (96%) versus the linear method (85% and 87%, respectively).	Insufficient

ASD=adjacent segment disease; CI=confidence interval; CT=computed tomography

Table G-17. Key Question 13: Intraoperative neuromonitoring

Outcome	Studies (n)	Limitations	Consistency	Directness	Precision	Reporting Bias	Summary of Findings	Strength of Evidence
Fusion	No studies	NA	NA	NA	NA	NA	NA	NA
Pain	No studies	NA	NA	NA	NA	NA	NA	NA
Function	No studies	NA	NA	NA	NA	NA	NA	NA
Adverse Events: Neurologic Complications	2 NRSIs (N=34,155) ^{136,137}	High	Consistent	Direct	Precise	Undetected	IONM vs. no IONM: 1 NRSI: 0.22% vs. 0.17%, p=0.41 1 NRSI: 0.23% vs. 0.27%, p=0.84	Low

IONM=intraoperative neuromonitoring; NA=not applicable; NSRI=nonrandomized studies of intervention

Appendix H. Appendix References

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