Protocol

Title: **OUTPATIENT Posterior Cervical Decompression, Instrumentation, and Fusion: the First 100 Consecutive Cases**

Outpatient outcomes from PCDIF ERAS protocol

Version: v1.0 (10-27-2025)

IRB #: 2025-919

Corresponding author / PI: Thomas Wascher

Study sites: The Advanced Spine Center, Neenah, Wisconsin and The NeuroSpine Center of Wisconsin, Appleton, Wisconsin

Protocol Synopsis

Design: Prospective (with retrospective elements of inpatients) observational cohort of consecutive outpatient with PCDIF surgery adherence to an ERAS protocol. A historical/secondary inpatient cohort is used as a non-assigned comparator for complication outcomes. Participants were not prospectively assigned to interventions for research purposes.

Primary objective: Evaluate pre- to post-operative changes in safety, efficacy, and patient acceptance of ERAS protocol in outpatient setting.

Key secondary objective: Compare complication rates of outpatients with a previously collected inpatient cohort.

Key timepoints: Pre-operative baseline, 3-month follow-up; extended follow-up.

Primary outcomes: Neurologic signs/symptoms; patient-reported measures (VAS neck/arm pain, Oswestry Neck Pain index, modified JOA score, Nurick score) from baseline to 3-month follow-up. Odom criteria from 3-month follow-up to extended follow-up.

Key secondary outcomes: Complications and readmissions at 3-month follow-up and extended follow-up.

Analysis: Prespecified in SAP v1.0.

Study Glossary:

ASC — Ambulatory Surgery Centers

ASA — American Society of Anesthesiologists class

BMI — Body Mass Index

ERAS — Enhanced Recovery After Surgery

HIPAA — Health Insurance Portability and Accountability Act

JOA — Japanese Orthopaedic Association score

MRI — Magnetic Resonance Imaging

PCDIF — Posterior Cervical Decompression, Instrumentation, and Fusion

PHI — Protected Health Information

SAP — Statistical Analysis Plan

SPECT — Single-Photon Emission Computed Tomography

VAS — Visual Analog Scales

1. Objectives

Primary objective: The primary objective of this study is to evaluate pre- to post-operative changes in safety, efficacy, and patient acceptance of an ERAS protocol for PCDIF patients in the **outpatient** setting.

Secondary objective: The secondary objective in the study is to compare differences in complication risks between **outpatient** in this study and a separate **inpatient** cohort drawn from prior collections as well as from other literature sources.

2. Background & Rationale

In 2019, of the 1,620,000 instrumented spinal surgeries performed in the U.S., 40.2% were cervical.[1] Of these, an estimated 14.2% or 92,500 were performed via a posterior approach.[2] In the 2025 American Spine Registry, 23.8% of cervical surgeries were posterior fusions and 7.8% were laminectomies.[3] PCDIF is a key treatment for cervical spondylotic myeloradiculopathy but has typically been limited to inpatient status due to invasiveness, complication risk, and postoperative pain control challenges. ASCs have increasingly performed complex procedures, with <23-hour stays, with documented excellent results. While ASC data support the safety and efficacy of anterior cervical discectomy with fusion and instrumentation as well as cervical foraminotomy,[4-6] evidence for outpatient PCDIF and comparisons with inpatient series remain scarce.[7,8] Therefore, we developed an ERAS protocol and evaluate safety, effectiveness, and patient acceptance in the first 100 consecutive outpatient cohort by a single surgeon at a single ASC.

3. Eligibility Criteria

As previously documented in many previous publications addressing inpatient PCDIF, the most important factors in patient selection for outpatient PCDIF are clinical signs and symptoms of cervical myeloradiculopathy with corresponding radiographic findings that have not responded to conservative measures. Inherent in achieving optimal outcomes after surgery is maintaining the radiographic alignment of the spine in static and dynamic positioning, correcting abnormalities in sagittal balance when appropriate.

Inclusion**:** Patients eligible for participation in this study include those with signs and symptoms consistent with cervical myeloradiculopathy and radiographic (MRI and/or cervical myelogram) evidence of corresponding spinal cord and/or nerve root compression who have failed to improve with adequate (4-6 weeks) conservative treatment. The primary considerations for selecting the appropriate patient for outpatient PCDIF are:

- the extent to which the patient's symptoms adversely affect that patient's lifestyle after failing 4-6 weeks of conservative management;
- the degree to which the patient's signs and symptoms correlate with the radiographic findings, especially in those patients with MRI evidence of myelomalacia;
- the level of confidence by the surgeon that symptoms are due to posterior compression of the neurologic elements and/or instability.

Exclusion**:** Advanced age with severe osteoporosis, severe pulmonary and/or cardiac disease, severe co-morbidities (such as multiple previous strokes), and fixed cervical kyphosis (with a sagittal Cobb angle of greater than 5 degrees) are considered contraindications to outpatient PCDIF in this study. Additional patients excluded from outpatient PCDIF in this study include all those with

- personal or family history of malignant hyperthermia;
- prior history of the requirement for fiberoptic intubation;
- pseudocholinesterase deficiency;
- any patient not cleared from a pulmonary or cardiology standpoint; and
- patients with an ASA of greater than 3.

4. Study Design and Procedures

The design of this study is prospective (with retrospective elements in inpatients) observational cohort of consecutive outpatient PCDIF cases at ASC. No randomization or research driven assignment is

utilized in the study. Outpatient data primarily includes pre-operative assessment, 3-month post-operative assessment, and extended follow-up.

4.1 Patient Screening, Preoperative Assessment, and Procedure Eligible for Surgery (preop)

Eligible outpatients are selected based on the inclusion and exclusion criteria described in the previous section. Goals of treatment are improvement in pain and neurologic deficits by performing adequate decompression of the spinal cord and affected nerve roots, maintenance of normal sagittal balance, elimination of spinal instability, and avoidance of delayed adjacent segment breakdown. In cases of severe circumferential and/or congenital cord compression, planned two-stage procedures will be performed, especially for those patients with T2 and STIR-weighted signal abnormalities on MRI (consistent with myelomalacia). This patient population will be treated with initial anterior cervical decompression, fusion, and instrumentation (either via multilevel anterior cervical discectomies with insertion of titanium interbody cages or corpectomy using radius allograft strut graft, plus plating) followed at an interval of 7-14 days by PCDIF. Patients with prior anterior cervical region radiation therapy as well as patients with primarily multi-level posterior compression and congenital stenosis ("short pedicle syndrome") will be treated preferentially with PCDIF.

A thorough preoperative assessment will be required to ensure patient safety and successful outcomes. This will include a rigorous attempt to identify and mitigate risk factors associated with cardiac and pulmonary comorbidities, obesity, and airway challenges.

- Comorbid diagnoses requiring a pre-operative cardiac clearance consultation include known atherosclerotic heart disease, valvular disease, hyperlipidemia, and poorly controlled hypertension.
- Conditions warranting pre-operative pulmonary clearance include COPD and emphysema, asthma requiring chronic medication(s), long-term smoking history, and obstructive sleep apnea.

- Patients with pre-existing factors contributing to poor bone formation (diabetes, rheumatoid and psoriatic arthritis, chronic steroid use, tobacco abuse, chronic renal insufficiency, vitamin D deficiency, and osteoporosis) will require medical maximization before surgery (including evaluation with DEXA scanning) with strong consideration for use of an external electrical bone stimulator post-operatively.
- All nicotine-containing products must be absolutely discontinued for at least 6 weeks pre-operatively, confirmed by serum cotinine levels.
- All aspirin, non-steroidal anti-inflammatory agents, fish oils, and vitamin E supplements will be discontinued at least 14 days prior to the day of surgery.
- Patients will be instructed to take multivitamin, Vitamin C, and Vitamin D for at least 2 weeks prior and for 12 weeks after surgery.
- Non-diabetic patients with marked cord deformation and myelomalacia will be started on dexamethasone (4 mg PO tid) and omeprazole for 3 days prior to surgery, if appropriate.
- Patients with a BMI of greater than 50 will be given an opportunity to lose significant weight before undergoing general anesthesia. All patients with a BMI greater than 40, in addition to weight loss, will undergo a pre-operative evaluation with anesthesia for an airway assessment including measurement of thyromental distance, ability to tolerate the prone position, baseline pulse oximetry readings, and dyspnea on exertion.

Of significant importance to the overall patient experience and outcome will be preoperative education provided by a "care navigator." This will be one person whom the patient can reach with a single telephone call regarding any pre- or post-operative concerns. This arrangement promotes the concept of a personalized patient care coordinator to provide uniform comprehensive care. Education before the procedure includes explicit discussions regarding expectations with regard to and timing of withdrawal from narcotics, the absolute requirement to have discontinued all tobacco products, specific instructions

regarding post-operative activity, use of an external electrical bone stimulator (if necessary), and the need to provide medical optimization before surgery (weight loss, medical clearances, HgA1C < 8.0, treatment of osteoporosis, and bone disease, addressing poor dentition, etc.). Every patient will be expected to be ambulatory within two hours of emergence from general anesthesia, with the requirement to ambulate at least 3 miles a day after discharge. In addition, each patient's psychosocial situation will be carefully evaluated to make certain adequate at-home support can be relied upon after surgery.

4.2 Anesthetic Technique and Intraoperative Procedure

After obtaining informed consent to participate in the trial, each participating patient will be de-identified by being assigned a number for follow-up. Initial anesthetic technique includes 15 mg of extended-release morphine or 20 mg of slow-release oxycodone administered orally. Intravenous access in both upper extremities will be established, avoiding the antecubital vein to reduce potential complications during positioning. Two mg of midazolam will be routinely administered for anxiolysis with a carefully selected dose of glycopyrrolate (usually 0.2 mg) chosen to minimize secretions without causing significant tachycardia. Upon arrival at the OR, a timeout will be performed, and ASA standard monitors are applied, including a 3- or 5-lead EKG (depending on cardiac history). A noninvasive blood pressure cuff is placed on the forearm, and a pulse oximeter is applied to a finger. Once prone, an additional pulse oximeter will be applied to an earlobe to provide consistent readings unaffected by limb movement resulting from neuromuscular stimulation artifact. Neuromonitoring leads are applied, including leads to monitor ulnar and posterior tibial nerves bilaterally to avoid inadvertent pressure palsies. A BIS monitor is secured to track the depth of anesthesia, ensuring optimal sedation levels while minimizing excessive anesthetic depth. Baseline vital signs are obtained before administration of an additional 2 mg of midazolam IV and 0.5 mg of rocuronium to mitigate succinylcholine-induced fasciculations. If the patient exhibits a tendency toward hypertension at this point, administration of 50 mcg of fentanyl will be considered. Preoxygenation with 100% oxygen is conducted for two minutes before induction.

Typical induction includes lidocaine (50-100 mg IV), propofol (1.5-2.0 mg/kg IV), and succinylcholine (1.5 mg/kg) IV. Intubation is then performed with care taken to maintain the patient's neck in the neutral position using a two-piece rigid collar. A Glide scope will always be at hand for the difficult intubation. Once intubated, routine measures such as end-tidal CO2 monitoring and auscultation will be checked before bilateral gauze bite blocks (to prevent oral injury as a result of stimulation from neuromonitoring) are inserted. Once the ET tube is secured, 50-100 mg of propofol will be administered IV and a Mayfield-Kees three-pin head holder applied. The patient is then turned into the prone position onto gel rolls placed on a Jackson table with the neck maintained in the neutral position. Once prone, the cervical collar will be removed with special care taken to ensure that appropriate padding has been applied to all bony and soft tissue prominences. Neuromonitoring leads will then be adjusted as necessary and attention then directed to make certain that positioning of the arms has not impeded free flow of IVs. The ET tube is checked to make certain it is secure and ventilation is unimpeded. A propofol infusion of 100 mcg/kg/min is started. To preserve neuromonitoring integrity, sevoflurane is maintained below 0.5 MAC with use of fentanyl as supplemental anesthesia (150-200 mcg in total, titrated according to patient response). Close collaboration with the neuromonitoring technician will be required to maintain a balance between adequate anesthesia and optimal neuromonitoring feedback.

A forced warm air device and warmed IV fluids are used throughout the procedure. Due to the constraints posed by inhalation agents with regard to neuromonitoring, propofol infusion and incremental dosing of fentanyl and midazolam will be utilized to maintain an appropriate depth of general anesthesia. Antibiotics, 10 mg of dexamethasone, 1 mg/kg of tranexamic acid, and 4 mg of ondansetron will be administered before incision. Typical intraoperative fluid requirements are expected to be in the range of 2 liters.

Immediately before incision, 10 cc of 1% Marcaine with epinephrine are infiltrated into the operative site as well as over the posterior superior iliac spine (the site of bone marrow aspiration). Once complete midline exposure of the diseased levels has been accomplished, instrumentation will be performed

first, followed by decompression and then fusion. Laminectomies are to be performed using a rough diamond burr to create bilateral trough laminotomies at the diseased levels at the laminar-facet groove medial to the facet complex. Remnants of bone and ligamentum flavum are then carefully divided with small Kerrison rongeurs at the depths of both troughs. Ligamentum flavum at the interspace levels above and below the diseased levels are then carefully divided over the spinal canal again with small Kerrison rongeurs to permit removal of the laminectomies in a "lobster-tail" fashion, providing for a minimum of manipulation over the spinal cord. The operating microscope and microsurgery can then be utilized to expand the laminectomies bilaterally as required and to perform precise foraminotomies at affected levels. The laminectomy specimen is morselized as local autograft and added to morselized allograft and iliac crest bone marrow aspiration to complete the fusion material. Other uniform intraoperative considerations include liberal use of a radiofrequency/saline bipolar sealer, precise placement of instrumentation using intraoperative frameless spinal stereotaxy, use of a subfascial drain, and use of bupivacaine liposome injectable suspension (266 mg) into the margins of the wound to improve post-operative pain control.

4.3 Immediate Postoperative Procedure (≤ 23 hours)

Once the patient undergoes reversal of general anesthesia and extubation, emphasis on early mobilization and ongoing education regarding post-op activity by the nursing staff is paramount. Intravenous dilaudid or morphine will be utilized in the initial post-operative period as required. A single dose of ketorolac (30 mg) is provided IV. Long-acting narcotic analgesia is maintained with slow-release oxycodone or extended-release morphine sulfate at either 10 mg or 15 mg BID, respectively, for up to 23 hours while at the ASC and then bid for an additional 7 days after discharge. Forty tablets of either hydrocodone/acetaminophen (5/325 mg) or oxycodone/acetaminophen (5/325 mg) are provided at discharge as are prescriptions for weaning doses of dexamethasone (4 mg PO tid for three days, followed by 4 mg PO bid for 3 days, ending with 4 mg PO q D for 3 days), omeprazole, and a muscle relaxant. All patients will be discharged no later than the 23 hours after admission. If possible, the drain is removed prior to discharge, using a level of accumulation of 30-40 cc over the previous 8 hours as a gauge for removal.

All patients will be contacted by phone 24 hours after discharge, at which time maintenance of the walking program and use of a stool softener will be emphasized. Opportunity to call the care coordinator with questions or concerns is revisited on the call as well. Cervical immobilization will be continued for 3 months after surgery, during which all non-steroidal anti-inflammatory agents, omega-3 oils, vitamin E, and fish oils are held. Smoking as well as use of any nicotine products are strictly forbidden. Patients at high risk for poor bone formation will undergo submission for use of an external electrical bone stimulator. Follow-up with AP and lateral cervical X-rays are performed at office visits at 2 weeks and again at 6 weeks after surgery, with additional follow-up including flexion-extension x-rays at 3 months after the initial procedure.

4.4 Intermediate Follow-up (3 months ± 2–4 weeks)

All patients are evaluated in the office at 3 months after surgery at which time a complete neurologic examination is repeated, focusing on assessment of muscle strength, pinprick and vibratory sensation, gait, reflexes, resting tone, and pathological reflexes. Flexion-extension cervical spine x-rays are performed to rule out hardware failure, pseudoarthrosis, and adjacent segment breakdown. Computer records are checked for additional narcotic and muscle relaxant prescriptions outside of those allowed by the protocol. Any unexpected emergency room, hospital admission, or ambulatory care evaluations in the post-op period are evaluated as to their relationship to the index surgery (as representing a possible complication related to PCDIF). Each study patient is assessed with regard to VAS neck and arm pain scores, modified JOA Score, PDR Oswestry Score, Nurick scores, and Odom Criteria.

Modified JOA score refers to an internationally accepted grading scale for the management of degenerative cervical myeloradiculopathy. The modified JOA scale is scored from 1-18 points, with 18 being normal (asymptomatic). A lower score represents a more severe myelopathy than a higher score. The modified JOA comprises four parts: movement in the arms and hands; movement in the legs; sensation in the arms; and bladder control.

Nurick score refers to another internationally accepted grading scale for the measurement of the severity of degenerative cervical myeloradiculopathy according to the following grades:

- Grade 0: signs and symptoms of nerve rot involvement but without evidence of spinal cord involvement.
- Grade 1: signs of spinal cord disease but with no difficulty walking.
- Grade 2: slight difficulty in walking which does not prevent full-time employment.
- Grade 3: extreme difficulty in walking that requires assistance and prevents full-time employment and occupation.
- Grade 4: Able to walk only with someone else's assistance or the use of a walker.
- Grade 5: chair bound or bedridden.

Odom Criteria refers to a widely accepted 4-point rating system for assessing the clinical outcome after cervical spine surgery. The four categories are as follows:

- Excellent: no symptoms related to cervical disease. Ability to perform daily activities without limitation.
- Good: moderate symptoms related to cervical disease. Ability to perform daily activities without limitation.
- Satisfactory: slight improvement of symptoms related to cervical disease. Significant limitations to daily activities.
- Poor: no improvement in or aggravation of symptoms re4lated to cervical disease. Not able to perform daily activities.

4.5 Extended Follow-up (≥ 3 months)

Patients are contacted via telephone and specifically queried regarding residual neck and arm pain

to obtain ending (final) VAS scores, weakness and/or sensory loss, gait or coordination difficulties, and any additional treatment (including presentation to an emergency room or urgent care center) as well as surgery possibly related to the original PCDIF procedure. Computer records are checked for additional narcotic and muscle relaxant prescriptions outside of those allowed by the protocol. Odom criteria are assessed as well. Finally, each patient is queried as to subjective percent improvement as a result of PCDIF. In addition, each patient is queried as to whether he or she felt post-operative pain management was adequate according to the protocol and what could have been improved throughout the entire process.

5. Data Collection

Data are collected from preoperative periods through extended follow-up. The main parameters include demographics, medical history, neurologic signs/symptoms, imaging (x-ray and MRI), intraoperative metrics, early recovery metrics (≤23 hours), patient subjective assessments, and safety/acceptance outcomes (complications and readmissions).

5.1 Preoperative Data Collection (Baseline)

- Demographics: age, sex, insurance group, BMI, and workers' compensation.
- Pertinent past medical history: prior remote cervical surgery/adjacent segment disease; recent anterior cervical decompression, fusion, and instrumentation as a planned Stage I surgery prior to planned Stage II PCDIF.
- Cardiac and/or pulmonary consultations before undergoing general anesthesia.
- History of factors jeopardizing bone formation: diabetes mellitus, rheumatoid or psoriatic arthritis, morbid obesity, chronic renal insufficiency, chronic steroid use and impaired inflammatory response, osteoporosis, recent tobacco abuse.
- Signs and Symptoms

  a) Presence or absence of pre-operative upper extremity weakness and sensory loss, as well as gait abnormalities.

b) Presence or absence of abnormal myelopathic findings, including hyperreflexia, increased resting tone, and pathologic reflexes such as crossed reflexes, spread of reflexes, Babinski response, Hoffman's sign, inverted brachioradialis reflexes, and greater than 4 beats of ankle clonus.

c) Assessment of presenting signs and symptoms as cervical radiculopathy, cervical myeloradiculopathy, or neck pain with sagittal malalignment/instability.

- Subjective patient assessment scores

  a) VAS neck and arm pain.

  b) Oswestry neck pain index.

  c) Modified JOA Scores.

  d) Nurick Score.

- Radiographic Findings

  a) Analysis of AP, lateral, and flexion/extension plain films with regard to: translational instability (as defined by White and Panjabi); straightening of lordosis with mobile (non-fixed) kyphosis; and the presence or absence of pseudoarthrosis in patients previously undergoing remote attempt at cervical fusion.

  b) Analysis of MRI with regard to cord signal (myelomalacia) and cord deformity with flattening.

  c) Any additional imaging, including cervical myelography/post-myelography CT and bone scan with SPECT imaging.

5.2 Intraoperative Data Collection

- ASA rating as a well-accepted rating system used by anesthesiologists to determine anesthetic risk
- Levels of operation
- Analysis of the location and the number of screws inserted and the method of insertion (fluoroscopy assisted versus intra-operative frameless spinal stereotaxy).
- Intra-operative EMG screw stimulation recordings as well as any neuromonitoring abnormalities.
- Operative blood loss

- Intra-operative complications
- Total operative time
- Use of a drain post-operatively

5.3 Immediate Postoperative Data Collection (≤ 23 hours after admission)

- Summary of narcotic usage during Stage I and Stage II recovery
- Immediate post-operative concerns and/or complications
- Drain output and whether drain was removed prior to discharge
- Post-operative hemoglobin, hematocrit, and electrolytes

5.4 Intermediate Postoperative Follow-Up (discharge to 3 months after surgery)

- Complications of any kind, including presentation to a hospital emergency room for any reason post-operatively, including inadequate pain control
- Any additional narcotic prescriptions for operative site pain
- Analysis of any reoperation within 90 days
- Post-operative signs and symptoms

  a) Presence or absence of weakness, sensory loss, and gait abnormalities

  b) Presence or absence of hyperreflexia and pathologic reflexes.
- Radiographic findings: Assessment of hardware failure/pseudoarthrosis on AP and flexion-extension plain films
- Subjective patient-reported post-operative assessment scores (*detailed description in 4.4*)

  a) VAS neck and arm pain scores

  b) Modified JOA scores

  c) PDR Oswestry scores

  d) Nurick scores

  e) Odom criteria

5.5 Extended Postoperative Follow-Up (after 3 months following surgery)

- Total follow-up period (in days)

- Subjective post-operative end assessment

  a) Percent improvement

  b) Ending VAS neck and arm pain scores
- Any additional cervicothoracic surgery during the total follow-up period
- Overall satisfaction with the pain control protocol post-operatively
- Odom criteria are used to evaluate patient's symptom improvement.

6. Endpoints

6.1 Primary Endpoint

- Neurologic signs and symptoms will be measured at baseline and 3-month follow-up. It includes presence/absence of weakness, sensory loss/paresthesias, abnormal gait, increased muscle tone, hyperreflexia, pathological reflexes; assessed at baseline and 3 months.
- Subjective patient assessments include VAS scores for neck and arm pain, Oswestry neck pain index, modified JOA scores, Nurick scores, and Odom Criteria scores. VAS scores will be measured at baseline, 3-month follow-up, and extended follow-up. Oswestry, JOA, and Nurick scores will be assessed at baseline and 3-month follow-up. Odom scores will be evaluated at 3-month follow-up and extended follow-up.

6.2 Secondary Endpoint

- Complications and readmissions will be monitored and recorded from the day of the index surgery throughout the extended follow-up.

7. Sample Size

The outpatient cohort includes 100 consecutive cases over 5 years. No *priori* power analysis was calculated. The sample size reflects all eligible cases in the study window. In addition to descriptive statistics, the primary inferential analyses will be McNemar and Wilcoxon signed rank tests. A sample size

of 100 is sufficient to reach high power (>.99) with a moderate effect size in Wilcoxon signed rank (Cohen's d = .5) with alpha level set at .05. For the McNemar tests, we anticipate observing 30-60% patients reporting positive signs/symptoms prior to the surgery and an improvement rate of 70% (the percentage changes from positive at baseline to negative at follow-up). With sample size of 100, the discordant pairs will be 21-42. If no new-onset positive symptom is reported in the follow-up, the McNemar test has power > .99. If under a more conservative effect where discordant odds ratio is 3 (10-35% patients report new positive symptoms, depending on the baseline prevalence), it will still yield to power .72-.9. Therefore, sample size of 100 is sufficient in this study.

8. Statistical Analysis Summary (Full details in SAP v1.0)

Descriptive statistics will be used to report baseline characteristics by sex. Continuous variables are summarized with mean, standard deviation, median, and range, and categorical variables are summarized with frequencies and percentages.

For the primary endpoints on outpatients only, McNemar tests will be conducted to assess binary variable changes from baseline to 3-month follow-up (e.g. signs/symptoms). Friedman and Wilcoxon signed rank tests will be used to examine the changes of VAS scores over 3 time points. Wilcoxon signed rank tests will also be performed in the other subject-report assessments from baseline to 3-month follow-up. Marginal homogeneity tests will be conducted to compare Nurick and Odom criteria score changes between the two time points.

For the secondary endpoints comparing complication rates between outpatients and inpatients, Fisher's Exact tests will be performed.

9. Data Management, Privacy & HIPAA

- **PHI elements:** After obtaining informed consent to participate in the trial, each participating patient will be de-identified by being assigned a unique number for follow-up.

- **Storage & access:** All data will be stored on hard copy worksheets and spreadsheets available only to the primary author and his nurse practitioner. All study information will be protected according to HIPPA compliance in all instances.
- **De-identification:** participants' unique number is included in the dataset for analysis. No PHI will be shared externally.
- **Retention & destruction:** All data will be preserved for a period of 10 years after completion of the study in compliance with HIPPA rules and the IRB approval. A HIPPA Waiver of Authorization has been approved as it relates to the conduct of the study as delineated in the IRB approval letter.
- **Consent/waiver:** Informed consent will be obtained for all patients involved in the study. Consent for participation in the study is to be obtained prior to surgery. All patients will be informed that de-identified outcome data will be compiled in all surgical cases to compare with previously published statistics for purposes of patient education and pre-operative teaching. They are not obligated to participate in the data collection process and may opt out at any point in their treatment.

10. Monitoring & Quality Assurance

This project is at minimal risk level, and no DSMB is required. For quality control, adverse events are recorded per our clinic policy. Periodic data checks will be performed monthly to insure data is being collected as to protocol and according to HIPPA compliance,

11. Registration & Dissemination

This study was reviewed by the MetroWest Medical Center Institutional Review Board and approved with a reference number of 2025-919. As this is an observational study, it does not require a clinical trial registration. Results will be submitted to NEJM. SAP v1.0 and Protocol 1.0 are provided as Supplementary Appendix.

Reference

1. Dyrda L. Surgeons perform 1.62 million instrumented spinal fusions per year in the U.S.: 5 things to know. Becker's Spine Review. April 5, 2019. https://www.beckersspine.com/spine/surgeons-perform-1-62m-instrumented-spinal-fusions-per-year-in-the-us-5-things-to-know/.

2. iData Research. Spinal implants market, United States: how many spinal fusions are performed each year? Market synopsis and brochure. May 25, 2018 https://idataresearch.com/products/spinal-implants-market-united-states/.

3. American Spine Registry. 2025 Fact Sheet: A Partnership Between American Association of Neurological Surgeons and American Academy of Orthopedic Surgeons. www.AmericanSpineRegistry.org. 2025:21-28.

4. Adamson T, Godil SS, Ehrlich M, et al. Anterior cervical discectomy and fusion in the outpatient ambulatory surgery setting compared with the inpatient hospital setting: analysis of 1000 consecutive cases. J. Neurosurg Spine 2016;24:878-884.

5. McGirt MJ, Rossi V, Peters D, et al. Anterior cervical discectomy and fusion in the outpatient ambulatory surgery setting: analysis of 2000 consecutive cases. Neurosurgery 2020:E310-315.

6. Rossi V, Asher A, Peters D, et al. Outpatient anterior cervical discectomy and fusion in the ambulatory surgery center setting: safety assessment for the Medicare population. J Neurosurg Spine 2020;32:360-365.

7. Badiee R, Mayer R, Pennicooke B, et al. Complications following posterior cervical decompression and fusion: a review of incidence, risk factors, and prevention strategies. Journal of Spine Surgery 2020;6:323-333.

8. Youssef J, Heiner A, Montgomery L, et al. Outcomes of posterior cervical fusion and decompression: a systematic review and meta-analysis. Spine J 2019;19:1714-1719.