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Clinical and Radiological Outcomes of Posterior Cervical Fusion Supplemented with Interfacet Spacers

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Background and Rationale

Posterior cervical fusion surgeries are performed for degenerative cervical conditions, cervical deformity, cervical tumors, and cervical trauma. They are preferred over an anterior approach when the pathology is located posterior to the spinal cord or when multiple levels must be addressed. Degenerative cervical spondylosis contributes to loss of disc height, facet arthropathy and hypertrophy, and retrolisthesis of the vertebral bodies, all of which can lead to foraminal stenosis, or narrowing around the exiting nerve roots [1]. This is often accompanied by loss of cervical lordosis [1]. During a posterior fusion operation, the restoration of cervical lordosis can worsen this foraminal stenosis and lead to iatrogenic radiculopathy with and estimated incidence between 2.4-50% [1]. Cadaveric studies have shown the insertion of interfacet spacers in the cervical spine increase foraminal height, and serve to indirectly decompress the exiting nerve roots [1]. Another common complication of cervical spine surgery is C5 palsy, which has been reported in 4.6% of patient undergoing posterior cervical spine decompressive procedures, including decompression and fusion. Patients suffering from iatrogenic C5 palsy have significantly increased recovery times, and often require additional services such as imaging studies (CT, MRI) and increased need for physical and occupational therapy, thus increasing costs. Given the ability to decompress the neuroforamen with interfacet spacers, they could potentially be an effective technique for reducing the incidence of C5 palsy.

The use of cervical interfacet spacers (CIS; CORNERSTONE® Facet MicroGrafts, Medtronic, Minneapolis, MN) is a relatively novel technique shown to be useful for posterior fusion to address symptomatic pseudoarthrosis (fusion failure) after anterior cervical arthrodesis [2]. CIS have a relatively large osteoconductive surface area and are placed under tension in the interfacet space, which together favorably influence bony fusion [2]. Current techniques for posterior cervical fusion rely on graft placement using bone extenders placed in the posterolateral space, which is not under a compressive load. Wolfe's law dictates that certain amounts of loading of bone grafts is required to achieve bony fusion [3]. Therefore, the use of CIS could potentially increase fusion rates after posterior cervical arthrodesis procedures and reduce or eliminate the need for use of bone graft extenders. Reassuringly, radiologic studies have shown that despite the increase in foraminal height, the use of CIS does not lead to loss of cervical lordosis [4].

Study Objective

To date, there have been no prospective studies examining the use of cervical interfacet spacers. We propose to undertake a prospective study to assess fusion rates and cervical sagittal parameters following posterior cervical arthrodesis procedures supplemented with CIS.

Primary Outcome Measures

The primary outcome measures will include (i) the rate of cervical fusion measured on post-operative radiographs and CT scans performed at 2-years and (ii) cervical sagittal alignment parameters as measured on post-operative radiographs.

Secondary Outcome Measures

The secondary outcome measures will include post-operative patient reported outcomes including NRS, NDI, and SF-36 RAND. As well, all neurological adverse events will be prospectively collected.

Study Plan

Patients undergoing posterior cervical arthrodesis procedures for spondylosis supplemented with CIS involving three or more segmental levels in the subaxial cervicothoracic spine (between C2-upper thoracic) will be asked to participate in this prospective cohort study.

Inclusion Criteria

- ≥ 18 years old
- Symptomatic multi-level degenerative spondylosis necessitating posterior cervical arthrodesis in the subaxial cervicothoracic spine (between C2-upper thoracic).
- Surgery performed within the Department of Neurological Surgery at The Ohio State University Wexner Medical Center (OSUWMC)

Exclusion Criteria

- Traumatic injury
- Previous spinal fusion surgery
- Co-morbidity requiring medication use that may interfere with bone or soft tissue healing (i.e., high dose oral or parenteral glucocorticoids, immunosuppressive agents, methotrexate) – at discretion of investigator
- Severe co-morbidities (e.g., heart, respiratory, or renal disease)
- Recent (<3 yrs) or co-incident spinal tumor or infection
- Concurrent involvement in another investigational drug or device study that could confound study data
- History of substance abuse (recreational drugs, prescription drugs or alcohol) that could interfere with protocol assessments and/or with the subject's ability to complete the protocol required follow-up
- Subjects who are pregnant or plan to become pregnant in the next 24 months
- Prisoner

Study Procedures

All patients enrolled in the study will be followed according to the study schedule (Table 1).

Patient demographic and pre-operative clinical information will include:

- Name
- Age

- Sex
- Race (self-reported)
- Vitals
- Height, weight and body mass index (BMI)
- General medical/surgical history
- Medication regimen
- Smoking status (current, former, never)
- History of alcohol/substance abuse
- Numerical rating scales for neck pain and arm pain
- SF-36 RAND
- Neck Disability Index
- Neurological Assessment (strength, sensory, reflexes, Hoffmann's response, Spurling's test)
- Duration of disease
- X-rays, CT, and MRI as available

Patient surgical details to be collected will include:

- Diagnosis
- Date of surgery
- Operative Index levels
- Operative time (incision open to close)
- Implants used
- Length of hospital stay
- Estimated blood loss / Surgical complications
- Somatosensory and motor intraoperative monitoring reports

Post-operative clinical information will include:

- Medication regimen
- Numerical rating scales for neck pain and arm pain
- SF-36 RAND
- Neck Disability Index
- Neurological Assessment (strength, sensory, reflexes, Hoffmann's response, Spurling's test)
- X-rays, CT, and MRI as available

Fusion determination

Fusion success will be assessed separately by a radiologist and a spine surgeon with no knowledge of clinical outcomes. Twelve-month X-rays will be evaluated to determine whether there is any motion at each segmental level. Fusion will be deemed to have occurred if 1) there is no change in the Cobb angle of the respective level on dynamic flexion and extension views and 2) the subjects' 2 year CT scan shows evidence of fusion mass posterolaterally at that level, using a modified version of the Lenke posterolateral fusion scale [5].

Study Calendar

	Enrollment	Surgery	Discharge	42 (± 7) Days	84 (± 14) Days	180 (± 30) Days	365 (± 60) Days	730 (± 60) Days
Informed consent	X							
Medical Hx	X							
Clinical outcomes (NRS, NDI, SF-36 RAND)	X			X	X	X	X	X
Neurologic Assessment	X		X	X	X	X	X	X
X-rays (AP/Lateral, Flexion and Extension)	X		X	X	X	X	X	X
CT Scan	X							X*

* research only procedure (not standard of care)

Only the CT scan at 2 years is a for research procedure. All other procedures, including the X-rays and the CT scan at enrollment, are standard of care.

Number of Patients

A sample size of 45 patients was calculated to detect a clinically significant treatment effect of CIS (90% power; alpha = 0.05, 2-sided; 10% lost-to-follow up). This calculation was performed with the assumption that subjects treated with posterior cervical arthrodesis procedures supplemented with CIS who successfully fuse by 1 year comprise 94% [6] of patients enrolled as compared to standard fusion rates seen as low as 76% [7].

Data Analysis

The primary objective of this study is to show that the use of CIS can potentially enhance fusion rates and sagittal parameters following posterior cervical fusion procedures. To compare the overall effect of treatment, the proportion of patients noted to meet “fusion success” will be compared to historical controls using the McNemar test for paired samples. In the situation that normality of the data is not achieved, the Mann-Whitney U test will be used. Clinical outcomes and adverse events will also be compared with that of historical controls. Secondary analyses will include comparative risk assessments of developing various adverse events such as post-operative C5 radiculopathy.

References

[1] L. Tan, C. Gerard, P. Anderson and V. Traynelis, "Effect of machined interfacet allograft spacers on cervical foraminal height and area," *Journal of Neurosurgery: Spine,* pp. 178-182, 2014.

[2] M. Kasliwal, J. Corley and V. Traynelis, "Posterior Cervical Fusion Using Cervical Interfacet Spacers in Patients with Symptomatic Cervical Pseudoarthosis," *Neurosurgery,* pp. 78, 661-668, 2016.

[3] P. Mummaneni, S. Meyer and J. Wu, "Biological approaches to spinal instrumentation and fusion in spinal deformity surgery," *Clinical Neurosurgery,* pp. 58, 110-116, 2011.

[4] L. Tan, D. Straus and V. Traynelis, "Cervical interfacet spacers and maintenance of cervical lordosis," *Journal of Neurosurgery: Spine,* pp. 22, 466-469, 2015.

[5] G. Fogel, J. Toohey, A. Neidre and J. Brantigan, "Fusion assessment of posterior lumbar interbody fusion using radiolucent cages: X-ray films and helical computed tomography scans compared with surgical exploration of fusion," *Spine Journal,* pp. 8(4): 570-577, 2008.

[6] M. Turel, M. Kerolus and V. Traynelis, "Machined cervical interfacet allograft spacers for the management of atlantoaxial instability," *Journal of Craniovertebral Junction & Spine,* vol. 8, no. 4, pp. 332-337, 2017.

[7] I. Elboghdady, M. Maaieh, A. Marquez-Lara, B. Skovrlj, J. Ahn, K. Aboushaala, S. Leblang, K. Singh and S. Qureshi, "Fusion rates following Posterior Cervical Laminectomy and Fusion Surgery: A Systematic Literature Review," in *SMISS Global Forum 2014*, Miami, FL, 2014.