POLYFIX DCM (What is the role of fixation for multi-level Degenerative Cervical Myelopathy undergoing posterior surgery?)

Research Question

What is the clinical and cost-effectiveness of fixation for multi-level Degenerative Cervical Myelopathy undergoing posterior surgery?

Background

Degenerative Cervical Myelopathy [DCM] is a common and disabling condition, caused by arthritic changes in the cervical spine that compress and injure the cervical spinal cord. These result in a progressive, slow-motion spinal cord injury (1). DCM is estimated to affect up to 2% (2) of adults and leads to a progressive loss of dexterity, gait disturbance, imbalance, bladder disturbance, and in severe forms incontinence and tetraplegia (1). Surgery is the only effective treatment. Removing the pressure on the spinal cord is able to stop disease progression and offer meaningful, albeit incomplete, recovery. International guidelines recommend it for moderate to severe and any progressive disease (3). Many patients suffer from multilevel degeneration in the cervical spine, requiring more extensive surgery from the back (posterior laminectomy). There is significant dispute as to whether decompression alone is sufficient or whether the spine should also be 'fixed' using metal implants. The main (untested) rationale for fixation is that the injured spinal cord benefits from reduced motion and that surgery results in less instability or consequent deformity (which may also benefit patients).

However, fixation requires additional skill, and is out of scope of some surgeons treating DCM (including general neurosurgical practice), thus restricting the treatment to specialist spine surgeons. It also entails higher costs, increased operative time, and leads to reduced mobility of the neck.

The overall aim of the POLYFIX DCM is to define best practice in the use of posterior spinal fixation for individuals undergoing multi-level posterior surgery for DCM.

Objectives and Methods

Does a strategy of decompression (laminectomy) with fixation improve functional outcome of adults with multi-level (3 or more levels) DCM treated posteriorly compared to a strategy of decompression (laminectomy) alone?

The description of the trial in terms of **P**atients, **I**ntervention, **C**ontrol, **O**utcome is:

P: Adults (>18) with a diagnosis of DCM, scheduled to undergo treatment at 3 or more levels
I: Posterior Decompression and Fixation (**Laminectomy and Fusion**)
C: Posterior Decompression (**Laminectomy**)
O: mJOA (Modified Japanese Orthopaedic Association)

Timelines for delivery

Ten sites, participating in the internal pilot will be opened for recruitment by 1st January 2022. The internal pilot will be completed by 1st September 2022. The study will progress to a substantive phase, if the internal pilot is successful. For the substantive phase, an additional 20

sites (30 sites in total) will be opened and recruitment completed by 1st April 2025. Allowing a further 24 months to complete follow up and 6 months for close down, the trial will complete 1/7/2027 (75 months in total).

Total sample size required is a total sample size of 394 participants under equal randomisation will provide 90% power (accounting for 10% drop out rate) to detect a change of 1 from baseline on the mJOA scale (assuming a standard deviation [SD] of 2.89), using a two-sided t-test at a 5% significance level.

Patient Inclusion Criteria

Inclusion Criteria	Exclusion Criteria
Adult patients (aged 18 or over) with DCM scheduled for posterior surgery involving 2 or more laminae.	Mild, non-progressive DCM (Defined as a mJOA Score of >16) Presentation in context of acute trauma (e.g. Central Cord Syndrome or Spinal Cord Injury) Laminoplasty, Skip Laminectomy

Site Considerations

We have estimated annual, per site recruitment at 4-8 patients.

Principal Investigator (PI), will require competency to perform both techniques. However, the performing surgeon does not need to be able to perform both techniques:

As a pragmatic trial, this is deemed acceptable as (1) expertise did not influence outcome for laminectomy alone, in large retrospective multi-centre study (N=675) (2) this more closely aligns with routine practice in some centres, where surgical care is triaged and allocated to surgeons depending on required expertise to better manage operative case load.

Procedural competency will be defined as performing or supervising 5 or more of a procedure per year.

Treatment (delivered <18 weeks of listing) and follow up is conducted in-line with routine care.

The majority of endpoints will be collected centrally.

Schedule of Assessments [Centrally Collected – Telephone or Post]

Primary End Point	**Secondary End Points**	
mJOA	**Patient Reported Outcome Measure**	**Clinician Recorded Outcome Measure**
	Pain • Neck Disability Index	Radiology (Dynamic / Neutral X-Ray) - *Sent centrally for analysis*

	• Brief Pain Inventory • VAS Neck and Arm Pain • Doleur Neuropathique (DN4) • Michigan Body Map (Pain Location) Quality of Life • SF36v2 EQ5D	• Alignment • Fusion • Movement Healthcare Usage • Length Hospital Stay / Operation • Complications Adverse Events

FUSION4DCM?
CONSORT Diagram