DCM Modeling

DCM Modeling **Degenerative cervical myelopathy: Treatment implementation through perioperative neurophysiology, simulation and modelling with AI integration**	
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D3.2 Pre-operative and follow-up evaluation protocol

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D3.2 Pre-operative and follow-up evaluation protocol

Version history

Version	Description	Date of completion
0.1	Table of Contents (ToC)	
0.2	Definition of study design	
0.3	Clinical evaluation protocol finalized	
0.4	Review	
0.5	Revised document	
1.0	Final document – submission to EC	

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**Dissemination Level: (PU) Public — fully open; (SEN) Sensitive — limited under the conditions of the Grant Agreement;

Executive summary

Deliverable D3.2 – Pre-operative and Follow-up Evaluation Protocol defines a standardized clinical, neurophysiological, and imaging evaluation framework for patients diagnosed with DCM. The primary objective of this deliverable is to establish a structured protocol for assessing neurological status, functional outcomes, and treatment effectiveness before and after surgical intervention, in alignment with WP3 – Patient enrollment, clinical and neurophysiological evaluation.

The proposed protocol is based on a prospective cohort study design, incorporating longitudinal assessments from the preoperative phase through postoperative follow-up at 3 and 12 months. Patients with clinically and radiologically confirmed DCM will be recruited from two neurosurgical centers in Italy and Serbia, ensuring adherence to ethical standards, Good Clinical Practice, and data protection regulations.

The evaluation framework integrates clinical scales, neurophysiological assessments, and imaging-based measurements. Clinical outcomes will be assessed using validated instruments such as the mJOA score and the Neck Disability Index. Neurophysiological evaluation will include SEPs and MEPs, as well as nTMS, applied as both a prognostic and follow-up tool in a subset of patients. Imaging assessments will focus on MRI and radiographic analysis of cervical sagittal alignment parameters.

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List of Abbreviations

Abbreviation	Explanation
ACDF	Anterior Cervical Discectomy and Fusion
DCM	Degenerative Cervical Myelopathy
FEM	Finite Element Modeling
mJOA	modified Japanese Orthopaedic Association (score)
MEPs	Motor Evoked Potentials
MRI	Magnetic Resonance Imaging
nTMS	Navigated Transcranial Magnetic Stimulation
SEPs	Somatosensory Evoked Potentials
SVA	Sagittal Vertical Axis

1. Introduction

Degenerative cervical myelopathy, characterized by spinal cord compression due to cervical spine degeneration, significantly impacts patient mobility and quality of life.

This prospective clinical study aims to evaluate the correlation between use of nTMS, value of clinical evaluation by certain clinical tests and evoked potentials (SEPs and MEPs) on treatment outcomes in patients diagnosed with DCM. Furthermore, this research intends to clarify whether the application of nTMS enhances postoperative recovery in patients diagnosed with DCM. Also the choice of surgical approach and postoperative changes in cervical alignment will be monitored as significant variables which could influence on treatment outcome.

In addition, the study will examine the use of 3D modeling and FEM as modern tools in the decision-making process related to the treatment of patients with DCM.

Objectives:

- To analyze the correlation between preoperative neurological status, cervical spine alignment, the type of surgical intervention (laminoplasty vs. anterior cervical discectomy and fusion), and clinical outcomes.
- To determine the effectiveness of nTMS in promoting recovery after surgery.
- To establish clinically relevant pre-and post-operative assessment tools to gauge surgical outcomes.
- To determine potential role of 3D modeling and FEM in treatment strategy and impact on outcome.

2. Study Design

This study will employ a prospective cohort design, involving longitudinal assessments of participants from preoperative through postoperative phases. **Figure 1** illustrates the workflow used to identify and define the clinical cohort prior to enrollment in the study. Patient data are first sourced from institutional patient databases, which contain demographic information, biomarker profiles, disease status, clinical details, and vital status. These data are used to perform cohort eligibility analysis and eligibility criteria modeling, enabling systematic cohort identification. In the context of this study, the cohort comprises patients with degenerative cervical myelopathy (DCM) who meet predefined inclusion and exclusion criteria. Eligible patients are adults aged 21–75 years with a clinical diagnosis of DCM confirmed by MRI evidence of cervical spinal cord compression, with or without signal changes, and who have consented to undergo surgical treatment via anterior or posterior approaches. Patients with prior cervical spine surgery, severe comorbidities likely to affect surgical outcomes, or inability to provide informed consent are excluded. The resulting cohort supports both eligibility criteria design and clinical trial site feasibility assessments before enrollment. Once identified, patients undergo standardized preoperative and postoperative clinical evaluations, including neurological, functional, radiographic, and neurophysiological assessments, with follow-up at 3 and 12 months to quantify surgical recovery and outcomes.

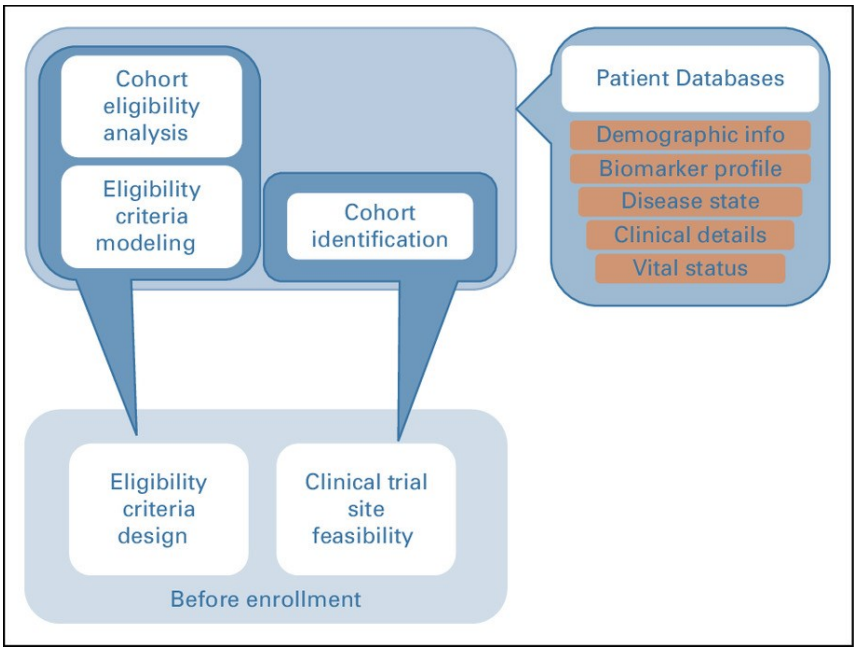

Figure 1. *Conceptual framework to support clinical trial optimization and enrollment workflows*

2.1 Patient Recruitment

Patients diagnosed with DCM, confirmed through clinical evaluation and radiological imaging, will be recruited from two neurosurgical centers – University Hospital Verona, Verona, Italy and University Clinical Center of Serbia, Belgrade, Serbia.

Clinical study protocol will adhere to valid (latest) versions of following documents:

1. Declaration of Helsinki, World Health Organization (www.wma.org)
2. Good Clinical Practice, International conference for Harmonization (www.ich.org)
3. General Data Protection Regulation (GDPR) (https://gdpr-info.eu/)

Participants will be informed about the study specifics, potential risks, and benefits prior to obtaining informed consent.

3. Inclusion and Exclusion Criteria

- Inclusion Criteria:
  - Patients aged 21-75 years.
  - Clinical diagnosis of DCM confirmed by MRI showing spinal cord compression with or without spinal cord signal changes.
  - Patients who consent to undergo surgical treatment – anterior and posterior surgical approach.

- Exclusion Criteria:
  - Prior cervical spine surgery or intervention.
  - Severe comorbid conditions that significantly affect surgical outcomes (e.g., cardiovascular diseases, infectious diseases).
  - Inability to provide informed consent.

4. Clinical Evaluations

Preoperative and postoperative evaluations will include:

- The mJOA score assessing neurological function.
- The Neck Disability Index to asses how neck pain is affecting patient's everyday life.
- Radiographic measurement of cervical sagittal alignment incorporating parameters such as C2-C7 SVA and T1 slope.
- SEPs and MEPs will be recorded to assess the functional integrity of the motor pathways.
- Among patient cohort from Verona University Hospital will be conducted pre and postoperative nTMS as a non-invasive neurophysiological assessment and treatment prognostic tool.

Postoperative assessments will mirror preoperative evaluations at 3 and 12 months following surgery to measure recovery.

5. Research Plan

Participants will be divided into two groups based on the type of surgical intervention:

1. Posterior surgical approach: A decompression method favorable for multilevel compression, with or without instrumentation.
2. ACDF: Typically used in single or double-level disease.

6. Imaging Controls

MRI and X-rays will be administered preoperatively to ascertain cervical alignment. Post-surgery imaging will be conducted to monitor decompression of the spinal cord, structural changes and spinal alignment.

7. Follow-Up Protocol

Participants will be followed up at 3 and 12 months after surgery, with assessment focused on functional outcomes through questionnaires (mJOA score, Neck Disability Index) and clinical evaluations by a neurosurgeon, as well as evaluation by imaging methods (MRI at 6 months after surgery and radiography at 3

and 12 months).

8. Anticipated Outcomes

This study aims to elucidate:

- The relationship between clinical data, spinal alignment and functional outcome.
- The efficacy of nTMS in predicting and enhancing postoperative recovery.
- The clinical utility of using SEPs and MEPs as adjuncts in evaluating surgical prognoses.

9. Conclusion

Understanding the interplay between nTMS and evoked potentials, as well as data provided from FEM and changes in clinical presentation, with surgical interventions may improved decision-making for DCM treatments, potentially guiding personalized care strategies that mitigate the progression of this severe condition. Integration of all these parameters may result in the creation of a new scoring system that could be helpful in the further course of treatment of these patients.

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