

# A Clinical Trial Evaluating a Total Disc Replacement in Patients with Cervical Disc Disease

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| <b>Submission date</b><br>21/05/2010   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>07/06/2010 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>07/06/2010       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
NUVA-CP-0904

## Study information

**Scientific Title**  
A Non-Randomised Controlled Clinical Trial Evaluating a Total Disc Replacement in Patients with Cervical Disc Disease

**Study objectives**

This study will be a non-randomized trial consisting of patients with single level (C3 to C7) symptomatic cervical disc disease who have not previously received fusion surgery at the same level, and have failed to improve with conservative treatment for at least 6 weeks prior to enrollment, or who present with progressive neurological symptoms or signs in the face of conservative treatment.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The medical ethics committee of El Centro Medico Hospital del Prado approved on the 15th of April 2010 (ref: NUVA-CP-0904)

### **Study design**

Non-randomized multicentre historically controlled

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Degenerative Disc Disease

### **Interventions**

Cervical spinal reconstruction

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Individual patient success at 24 months, tested using Blackwelders method for testing non-inferiority with delta of 10%.

Success is defined as:

1. Improvement in the Neck Disability Index (NDI) by  $\geq 15$  points at 24 months compared to Baseline
2. No device failures requiring revision, re-operation (including supplemental fixation), or removal from the patient
3. No device-related serious adverse event and
4. Maintenance or improvement of neurologic status (based on sensory, motor, and reflex assessment scores and observational gait analysis)

### **Key secondary outcome(s)**

1. Range of Motion (ROM) defined as more than 3 degrees total flexion / extension. If the ROM is less than or equal to  $3^\circ$  the patient will be defined as having 'non-motion'
2. Fusion (defined as  $\leq 3^\circ$  of ROM at the operative level, absence of radiolucent lines around  $\geq 50\%$  of the implant, and no displacement or migration of the device (defined as  $> 3\text{mm}$  abnormal

movement measured from AP and lateral plain films)

3. SF-36 improvement of  $\geq 15\%$  at 24 months compared to Baseline

4. Visual analog pain scale (VAS) improvement of  $\geq 20$  mm at 24 months compared to Baseline

5. Disc height from the lateral radiograph showing maintenance or improvement from Baseline at 24 months

### **Completion date**

31/12/2010

## **Eligibility**

### **Key inclusion criteria**

1. Age: 18-60 years of age (inclusive and skeletally mature)

2. A diagnosis of symptomatic cervical disc disease, defined as image-confirmed pathology: herniated disc, spondylosis, and/or loss of disc height. Spondylosis is defined as image-confirmed disc desiccation, loss of disc height, bridging osteophytes, and/or uncovertebral arthrosis. Loss of disc height is specified as a measurement of at least 25% less than an adjacent nonsymptomatic level, but with a minimum of 1mm height remaining

3. Functional neurological deficit (i.e., exhibits at least one sign associated with cervical level to be treated, including abnormal reflex, decreased motor strength, abnormal dermatome sensitivity, or pain in a dermatomal distribution);

4. Symptomatic level is C3-4, C4-5, C5-6 or C6-7 (one level)

5. Preoperative Neck Disability Index (NDI)  $\geq 30$  points (considered moderate disability; Vernon 1991);

6. Unresponsive to conservative treatment for  $\geq 6$  weeks, and/or exhibits progressive symptoms and/or signs of nerve root and/or spinal cord compression in the face of conservative treatment

7. Not pregnant, nor interested in becoming pregnant within the follow-up period of the study

8. Willing and able to comply with the requirements defined in the protocol for the duration of the study

9. Signed and dated Informed Consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

60 years

### **Sex**

All

### **Key exclusion criteria**

1. Prior cervical fusion, prior laminectomy (prior cervical laminotomy that has not violated the facets need not be excluded), and/or prior cervical facetectomy at the operative level
2. Requiring surgical treatment that would leave the patient with a postoperative deficiency of the posterior elements
3. Signal changes in the cord on preoperative T2-weighted MRI and/or clinically significant myelopathy which would be described as gait disturbance, loss of manual dexterity, or bowel or bladder incontinence/retention.
4. Radiographic signs of significant instability at operative level (> 3mm translation, > 11° rotation different from adjacent level)
5. Bridging osteophytes or motion < 3°
6. Radiographic confirmation of significant facet joint disease or degeneration
7. Chronic neck or arm pain of unknown etiology
8. Cervical fracture, anatomic anomaly, or deformity (e.g. ankylosing spondylitis, scoliosis) at the levels to which the prosthesis will be attached
9. Severe spondylolisthesis (greater than grade 1)
10. Endocrine disorders or connective tissue diseases
11. Rheumatoid arthritis or other autoimmune disease
12. Progressive neuromuscular disease, e.g., muscular dystrophy, multiple sclerosis
13. Chronic steroid users
14. Taking any medications or drugs in doses that are known to potentially interfere with the bone metabolism or soft tissue healing, which may include (but is not limited to) the following: inhaled glucocorticoids for asthma, corticosteroids, thyroid hormones, blood thinners (heparin, warfarin), gonadotropin-releasing hormone agonists for prostate cancer treatment, contraceptive medroxyprogesterone, lithium for bi-polar disorder treatment, anticonvulsants, aluminum-containing antacids, tetracycline
15. Osteoporosis to a degree that spinal instrumentation would be contraindicated (DEXA T-score less than or equal to -2.5; DEXA necessary only if patient exhibits risk factors for low bone mass as quantified in DEXA screening questionnaire)
16. Diabetes mellitus requiring insulin management
17. Presence of metastases or active spinal tumor malignancy
18. Body Mass Index (BMI) > 40
19. Active local or systemic infection, including AIDS, hepatitis
20. Having been enrolled in another investigational device study within the last 90 days
21. Having had another cervical device implanted that would interfere with the surgical approach, study or control device, or follow-up evaluations
22. Demonstrates 3 or more signs of nonorganic behavior, such as Waddells signs
23. History of substance abuse
24. Involved in spinal litigation
25. Mentally incompetent
26. Incarcerated

**Date of first enrolment**

26/05/2010

**Date of final enrolment**

31/12/2010

## **Locations**

**Countries of recruitment**

Mexico

United States of America

**Study participating centre**  
1200 Hilyard  
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United States of America  
97401

## Sponsor information

**Organisation**  
Nuvasive Inc. (USA)

**ROR**  
<https://ror.org/036dqy506>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Nuvasive Inc. (USA)

## Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration