



PARADIGM SPINE

the movement in spine care



Dynamic Cervical Implant

DCI™

Cervical Dynamic Stabilization



RECURRENT NECK PAIN DUE TO ADJACENT SEGMENT DISEASE:

THE RATIONALE FOR MOTION PRESERVATION

The gold standard in stabilizing the cervical spine still is Anterior Cervical Discectomy and Fusion (ACDF) with its well-known application and reliable stabilization.

Although the clinical outcomes are good, fusion is associated with several well-documented peri- and postoperative problems such as pseudarthrosis, instrumentation-related complications and adjacent segment disease.¹

Biomechanically, adjacent segments have to compensate for the loss of motion at the treated level. Changed motion patterns lead to abnormal load transmissions and increased stresses including but not limited to higher intradiscal pressures, increased facet joint stresses and abnormal intervertebral motion.² Radiographic studies report rates of degeneration of up to 92% of all cases and confirm what has been suggested in numerous biomechanical studies.³

While genetic and environmental factors may play an important role, rigid fusion also seems to be a significant risk factor for accelerated deterioration of adjacent segments. Matsumoto et al. observed that ACDF patients had a significantly higher incidence of progression in disc degeneration at the adjacent

segments. Although adjacent segment degeneration is not always symptomatic, clinical symptoms including neck pain, headache and stiff shoulder were significantly more frequent in patients with progressive degenerative changes.⁴

Recent publications of prospective randomized controlled trials comparing motion preserving implants with fusion suggest that patients with dynamic implants have a significantly lower risk of reoperations both at the index and adjacent level. At 5 years patients treated with ACDF had a nearly 5-times higher reoperation rate due to adjacent segment disease.⁵

Even though disc arthroplasty is an alternative, its indications are limited. Only a minority of the population affected by painful cervical degeneration are appropriate candidates for a total disc replacement.⁶

The **DCI™** implant bridges the gap between fusion and disc arthroplasty by addressing the potential downsides of fusion and by offering the advantages of motion preservation to a wider patient population.

DCI™ – Combining the advantages of the gold standard with motion preservation.

¹ Phillips FM, Carlson G, Emery SE, et al. *Spine* 1997; 22:1585-1589.

² Dmitriev AE, Cunningham BW, Hu N, et al. *Spine* 2005; 30:1165-1172.

³ Goffin J, van LJ, Van CF, et al. *J Spinal Disord* 1995; 8:500-508.

⁴ Matsumoto M, Okada E, Ichihara D, et al. *Spine* 2010; 35:36-43.

⁵ Delamarter RB, and Zigler JE. *Spine* 2013; 38:711-717.

⁶ Auerbach JD, Jones KI, Fris CI et al. *Spine J* 2008; 18:711-716.



COMBINING THE GOLD STANDARD WITH MOTION PRESERVATION



| DCI™ = | All the Benefits of the Gold Standard | + | Protection of the Adjacent Levels |
|---------------|--|----------|---|
| | <ul style="list-style-type: none"> • Stabilization of the affected segment • Protection of the neural structures • Restoration of segmental height and sagittal balance • Limited motion in axial rotation and translation to preserve facet joints • Single piece implant: no wear debris • Easy and safe application | | <ul style="list-style-type: none"> • Dampening and shock absorption at operated level • Physiologic kinematics at the adjacent segments |

"The Dynamic Cervical Implant (DCI™) has been developed to combine the advantages of the gold standard, fusion, with a motion preservation philosophy. This allows the surgeon to achieve one important treatment goal: Delaying fusion as long as possible to protect the adjacent segments.

The DCI™ implant was designed in a U-shape to fit into the anatomical geometry of the disc space. The DCI™ implant stabilizes the cervical spine while providing motion in flexion-extension, the main motion direction in the subaxial C-Spine.

It offers shock absorption, a main advantage compared to most disc prostheses. Protection of the facet joints by offering stability in rotation and translation allows to address a wide range of indications. Therefore degenerative arthropathy, a main cervical pain generator, remains an indication for DCI™ contrary to most arthroplasties."

Guy Matgé, MD, PhD

National Neurosurgical Department, Centre Hospitalier de Luxembourg and inventor of the DCI™

DESIGN RATIONALE

More than 9 years of clinical experience and more than 9,000 implantations worldwide have proven the clinical success of the **DCI™** implant. This device is ideal for cervical spinal stabilization after surgically addressing symptomatic cervical disc herniation, cervical degenerative disc disease and cervical canal stenosis.

Intelligent Implant Design

- Excellent fatigue strength and durability
- Single-piece design: no wear debris
- Anatomical design and anterior teeth preserve the integrity of the endplates
- Restoring force against kyphosis based on spring tension

Simplicity

- 12 anatomical sizes
- Color coded instrumentation
- Biocompatible titanium alloy
- Easy and precise application

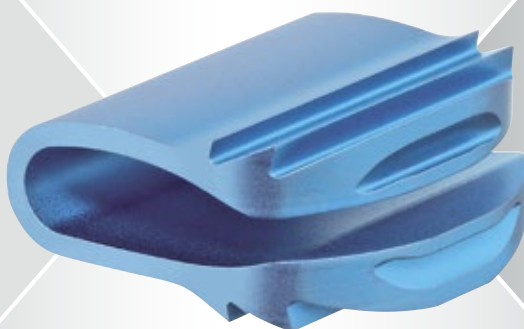
Functionally Loading and Motion Preserving

- Compressible in flexion
- Axial force shock absorption
- Offloads and protects the facet joints
- Load-sharing design

2-Part functional design

Intervertebral Stabilization

- Unique **DCI™** design allows for maximum endplate coverage and deep insertion
- Apex of the „U“ permanently maintains foraminal height and offloads facet joints
- Increased rotational stability for facet joint protection



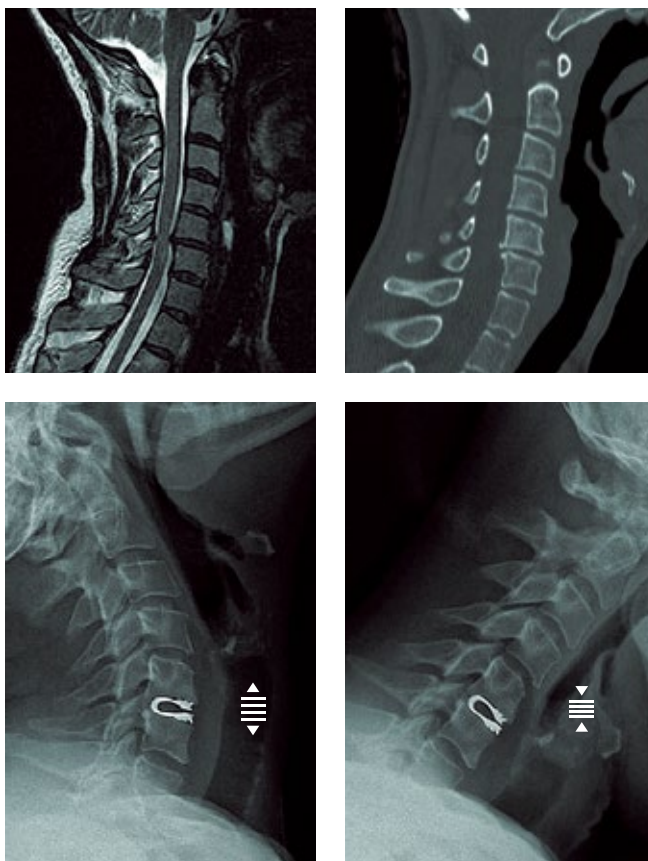
Motion Preservation

- Compressible in flexion
- Shock absorption of axial loads
- Preservation of physiologic index and adjacent segment kinematics



Indication

The **DCI™** implant is indicated for anterior implantation into the cervical disc space at one to three levels from C3 to C7. The **DCI™** controls segmental motion in cases of cervical disc herniation, cervical degenerative disc disease (DDD) and cervical canal stenosis (central or foraminal) with or without myeloradiculopathy in patients with or without neck pain.



DCI™ – Clinically and Scientifically Proven Concept

The concept and benefits of **DCI™** were confirmed by almost one decade of clinical experience together with modern radiographic and biomechanical research. The following pages introduce some of the most relevant studies.

For further information, please reference www.paradigmspine.com



CLINICAL DATA

In 2007, a prospective, multicenter postmarket surveillance study was initiated by Paradigm Spine to evaluate the clinical effectiveness and safety profile of the **DCI™** implant (Matgé G, Eif M, Herdmann J et al. BritSpine 2012). All patients were followed up for two years.

| Patient Demographics | |
|-----------------------|------------------|
| Patients | |
| Number of Patients | 247 |
| Follow-up Rate at 24m | 78.1% (n=193) |
| Demographics | |
| Female | 139 |
| Male | 108 |
| Mean Age (range) | 49 years (25-82) |

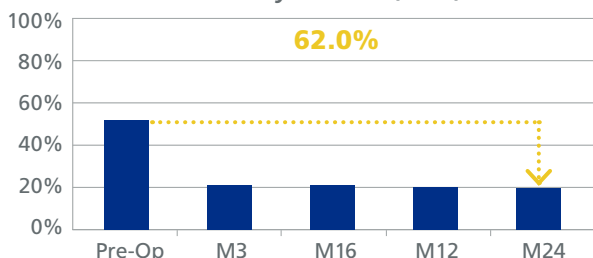
| Indications (multiple answers possible) | |
|---|-------------|
| Cervical Disc Herniation | 205 (83.0%) |
| Cervical DDD | 100 (40.5%) |
| Cervical Canal Stenosis | 92 (37.2%) |

| Treated Segments | |
|------------------|-----------|
| Cases | |
| Monosegmental | 215 |
| Bisegmental | 30 |
| Trisegmental | 2 |
| Treated Levels | |
| C3-C4 | 13 (5%) |
| C4-C5 | 35 (12%) |
| C5-C6 | 124 (44%) |
| C6-C7 | 109 (39%) |

| Perioperative Outcomes (avg.) | |
|-------------------------------|----------|
| Operative Time | 75.6 min |
| Estimated Blood Loss | 34.8 ccs |

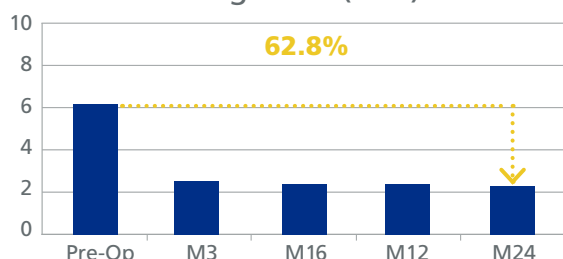
Clinical Outcome

Neck Disability Index (NDI)



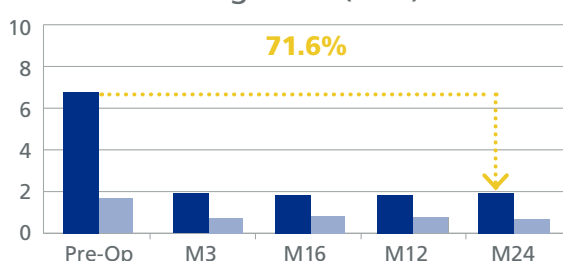
- The NDI shows a considerable improvement that is sustained over two years.
- Compared to preoperative values, patient improvement was 62.0% at 24 months.

Visual Analog Scale (VAS) Neck Pain



- The VAS for neck pain shows a considerable improvement that is sustained over two years.
- Compared to preoperative values, patient improvement was 62.8% at 24 months.

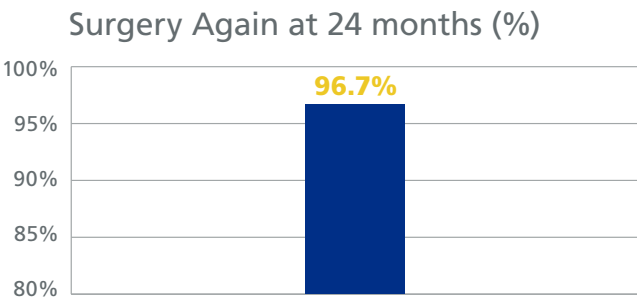
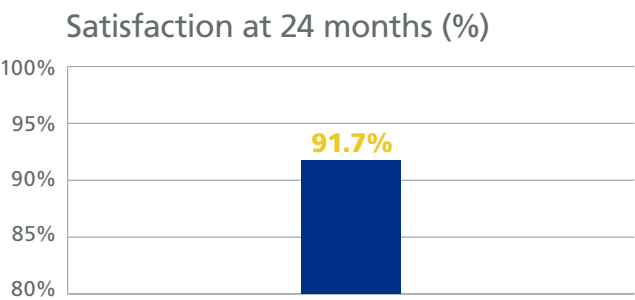
Visual Analog Scale (VAS) Arm Pain



- The VAS for arm pain shows a considerable improvement that is sustained over two years.
- Compared to preoperative values, patient improvement was 71.6% for the affected arm at 24 months.

■ Affected Arm (max) ■ Not Affected Arm (min)

Patient Satisfaction



- At 24 months, more than 91% of the patients were satisfied with their treatment.
- After 24 months, more than 96% of all patients reported that they would undergo surgery again.

Safety

Implant-related Adverse Events

The incidence of implant-related adverse events was low. Three out of 247 patients (1.2%) required revision surgery at the index level and were reoperated within 6 months postoperatively. In two cases, anterior migrations led to implant removals and fusion (n=1) or reinsertion of a larger height *DCI*TM implant (n=1). In one case persistent pain (cervicobrachialgia) led to an implant removal and fusion. No posterior migrations, implant deformations or implant breakages were reported.

| Implant-related Adverse Events | |
|--------------------------------|----------|
| Implant Breakages | 0 (0.0%) |
| Implant Deformation | 0 (0.0%) |
| Anterior Migrations | 2 (0.8%) |
| Posterior Migrations | 0 (0.0%) |

Reoperations (not at Index Level)

A total of three patients (1.2%) required additional surgery at another cervical or cervico-thoracic level. Two patients received further stabilization next to the adjacent segment, one was treated with another *DCI*TM implant (16 months postoperative), the other one with a fusion (12 months postoperative). One patient received a *DCI*TM implant at the cervico-thoracic junction 4 days after initial surgery at the level of C3-C4.

| Reoperations (not at Index Level) | |
|---|----------|
| Reoperations at Adjacent Segments | 0 (0.0%) |
| Reoperations at other Cervical or Cervico-thoracic Segments | 3 (1.2%) |

| Reoperations Details | | |
|----------------------------------|-----------------------------------|-----------|
| Initial Surgery | Reoperation | Timepoint |
| <i>DCI</i> TM , C3-C4 | <i>DCI</i> TM , C7-Th1 | 4d |
| <i>DCI</i> TM , C5-C6 | Fusion, C3-C4 | 12m |
| <i>DCI</i> TM , C6-C7 | <i>DCI</i> TM , C4-C5 | 16m |

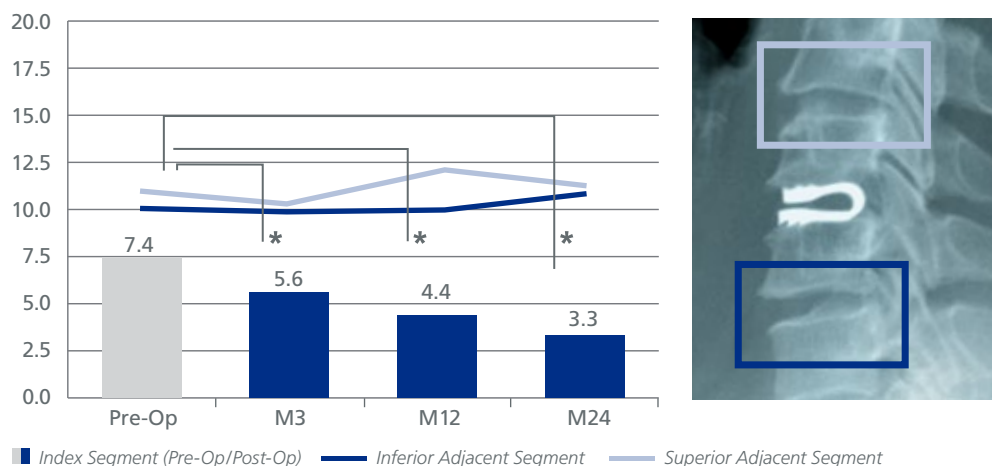
Summary:

The *DCI*TM implant is a clinically effective and safe solution for treating neck and arm pain in cases of cervical disc herniation, canal stenosis and DDD.

RADIOGRAPHIC DATA

An in-vivo radiographic analysis of the **DCI™** implant was performed utilizing a new functional X-Ray analysis method (FXA™, Aces GmbH). The radiographic data set consisting of a consecutive series of 57 patients from one clinical site (PD Dr. Jörg Herdmann, St. Vinzenz-Krankenhaus Düsseldorf) was examined. All patients were treated at one level. The Functional X-Ray Analysis was utilized to determine the Range of Motion, the Center of Rotation and the Disc Height, both at the index segment and the adjacent levels.

Range of Motion Analysis

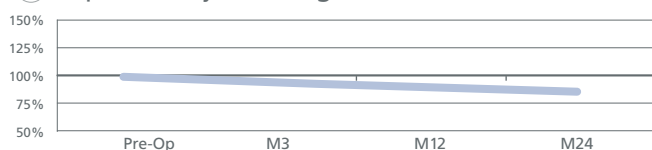


- The **DCI™** implant has a significant (*) stabilization effect at the index segment.
- The ROM at the adjacent segments remains mainly unchanged at all timepoints.

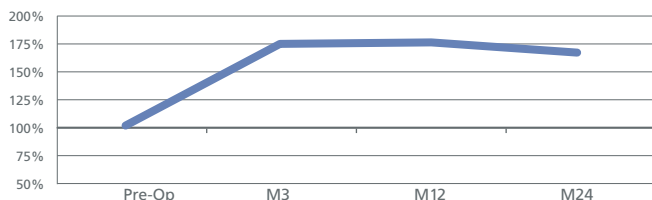
Disc Height Analysis

The disc height of the index and the adjacent segments was measured in the middle of the intervertebral space.

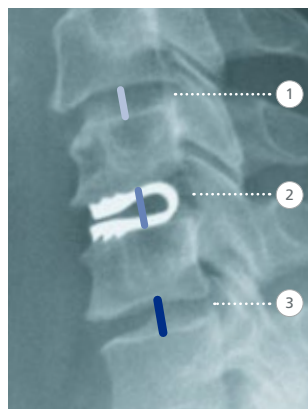
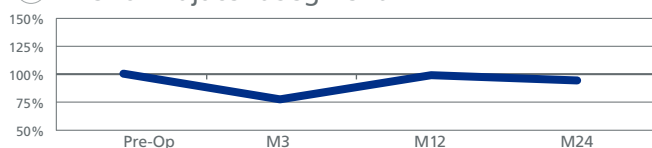
① Superior Adjacent Segment



② Index Segment



③ Inferior Adjacent Segment



Pre-Operative Disc Heights = 100%

- Disc height is restored at the index level and could be maintained over 24 months.
- At the adjacent segments the disc height remains mainly unchanged over time.

Center of Rotation Analysis

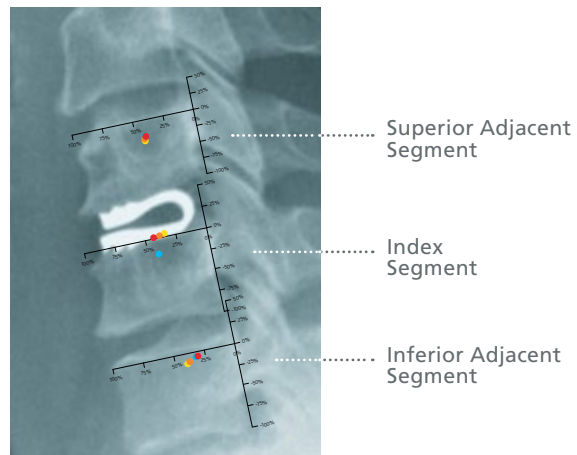
The median values of the mean Centers of Rotation (COR) over all patients have been calculated to compare the CORs at the different timepoints from baseline up to 24 months to each other.

COR (Pre-Op)

COR (Post-Op M3)

COR (Post-Op M12)

COR (Post-Op M24)



- The COR at the index segment moves slightly towards the endplate.
- The center of rotation at both adjacent segments remains mainly unchanged.

Summary:

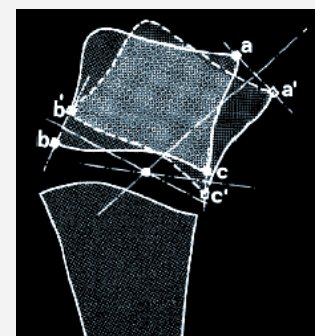
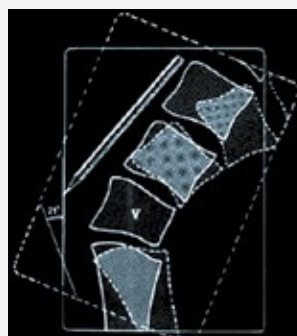
- The **DCI™** implant stabilizes the index segment, while preserving motion.
- The implant maintains physiologic kinematics at the adjacent segments.



Motion Analysis and Quantification of Functional X-rays

Functional X-Ray Analysis (FXA™) is an automatic software based technology to assess motion patterns for the most precise motion quantification and image analysis of medical images in terms of quantitative and qualitative parameters. This technology combines state-of-the-art digital image processing, object recognition and orientation algorithms, and utilizes vector and matrix math to compute relative motion in medical imaging. It is the most accurate method used in clinical science and practice with a standard deviation of $0.04^\circ \pm 0.13$ compared to manual methods with $0.17^\circ \pm 2.00$ for calculating the Range of Motion (ROM).¹

¹ Schulze, M et al. J Biomech 2011; 44.9:1740-1746.



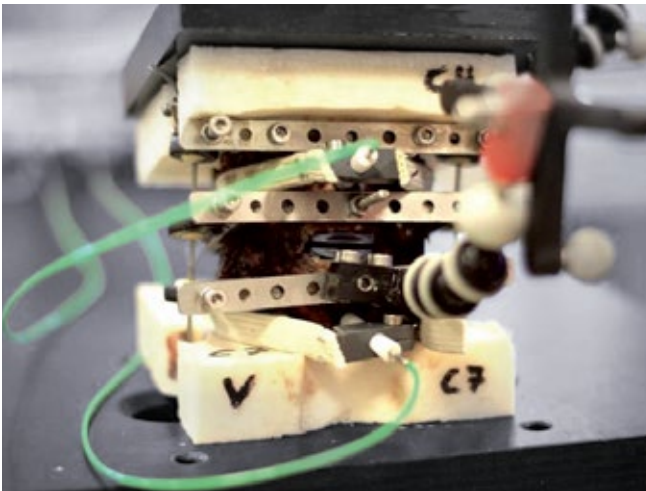
Evaluation of Surgical Treatment Using Functional Radiographic Images Depicting two Different Joint Positions

BIOMECHANICAL DATA

In a biomechanical study performed by the Laboratory for Biomechanics and Biomaterials of the Hannover Medical School (PD Dr. Daentzer, Dipl. Ing. Welke), 7 human cervical spine specimens from C4-C7 were used for treatment of the index level at C5-C6 according to the Multidirectional Hybrid Test Method developed by Panjabi.¹

The purpose of this study was to perform a biomechanical comparison between fusion (titanium cage + semi-rigid plate), total disc arthroplasty (ball and socket design) and the **DCI™** implant, and to examine their influence on the adjacent segments.

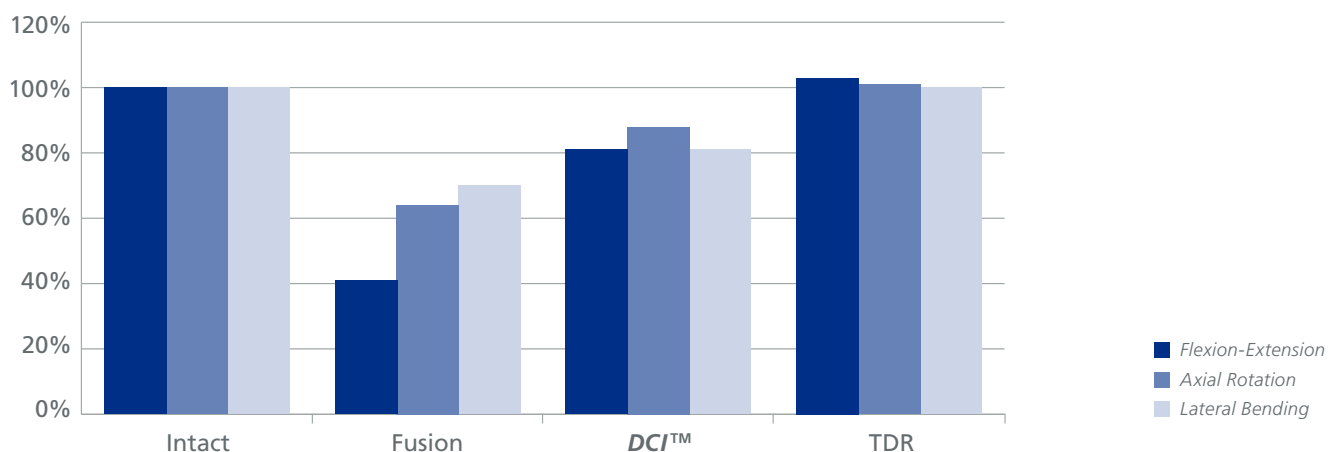
Initially, the intact state of the specimens was investigated and subsequently compared to the 3 different treatment options. Parameters were collected for the total Range of Motion, the segmental Range of Motion and the Intradiscal Pressure among others.



DCI™ Test Setup, Courtesy of Hannover Medical School

Range of Motion at the Index Level

Intact values have been normalized to 100%.

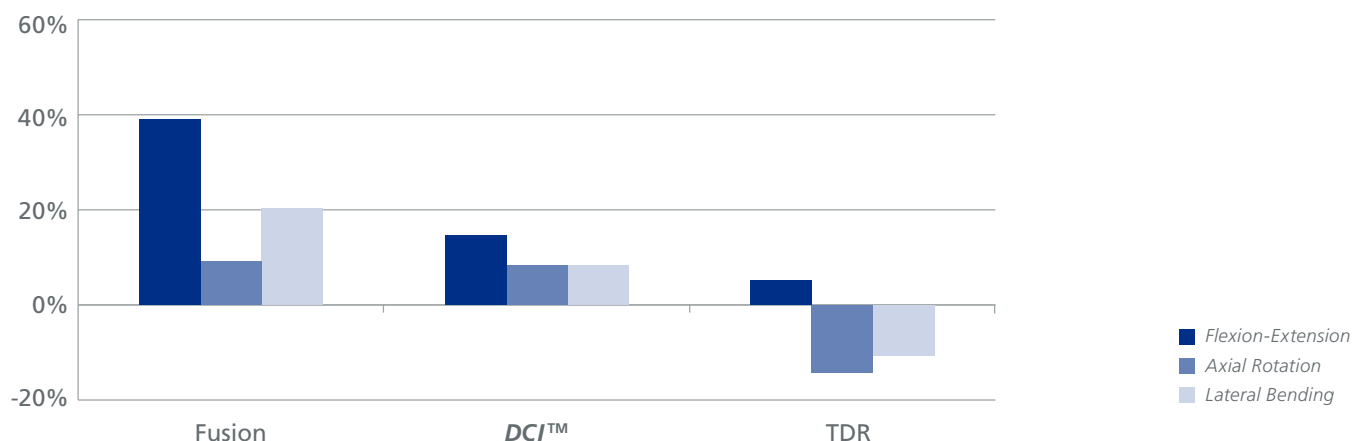


The **DCI™** implant has a stabilizing effect in all motion directions.

¹ Panjabi MM. Clin Biomech 2007; 22:257-65.

Range of Motion at the Superior Adjacent Segment

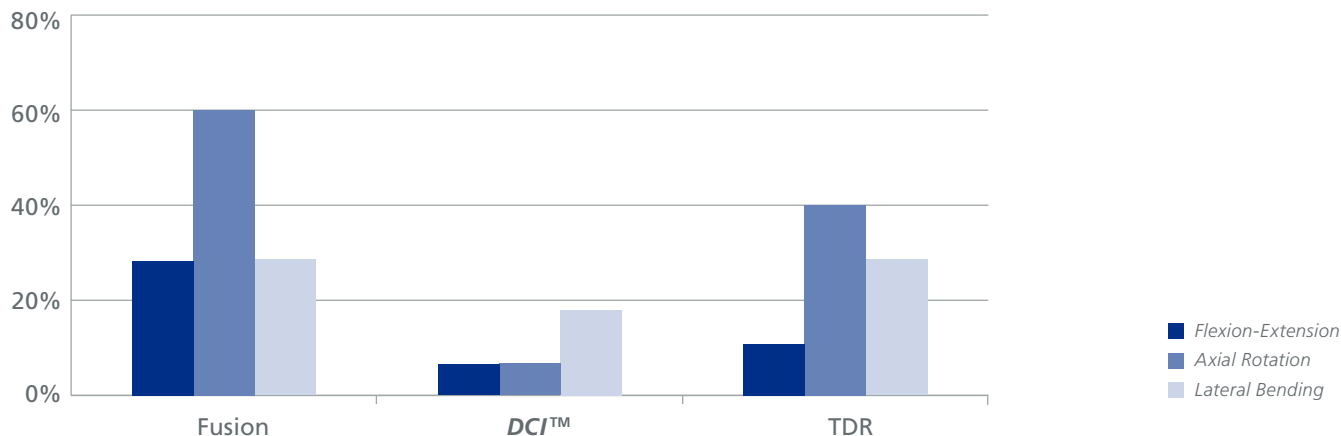
Values illustrate changes compared to the intact condition.



- The **DCI™** implant has only a minor effect on the ROM at the adjacent segment.
- Fusion presents an increase of 39% in Flexion-Extension.

Intradiscal Pressure at the Superior Adjacent Segment

Values illustrate changes compared to the intact condition.



- The **DCI™** implant has only a minor effect on the intradiscal pressure at the adjacent segment.
- Both, fusion and arthroplasty lead to higher disc pressure at the superior adjacent segment, especially in axial rotation.

Summary:

- The **DCI™** implant has a stabilizing effect on the treated segment leading to only minor changes in adjacent segment kinematics compared to fusion and TDR.
- Intradiscal pressure at the superior adjacent segment shows the least increase with the **DCI™** implant.

SURGICAL TECHNIQUE

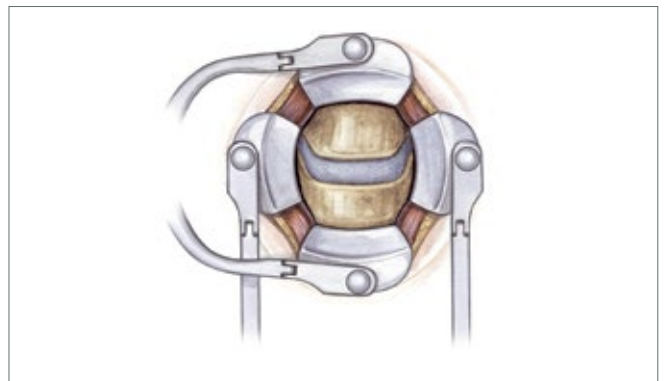
1. Preparation

The patient is placed in supine position with slight hyperextension of the neck supported by a neck roll.



Medial anterior approach to C3-C7 segments is utilized and a standard technique is applied to expose the affected disc level.

The disc space is distracted using the standard distraction technique



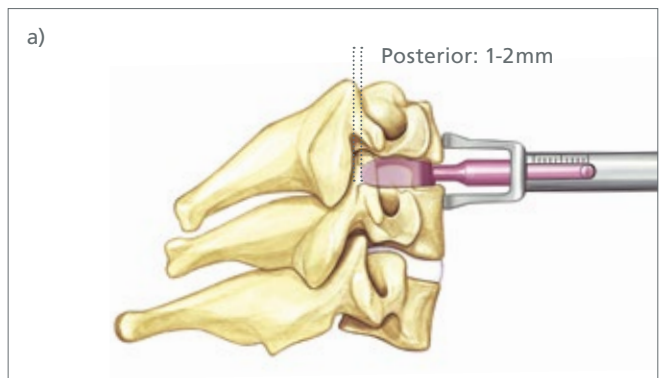
2. Decompression

Microsurgical decompression with complete discectomy is performed relieving all points of neural compression. The implant bed is prepared with curettes and burrs cleaning the endplates from disc tissue. Care has to be taken not to remove the subchondral bone. To avoid heterotopic ossification, it is not recommended to remove the anterior osteophytes.

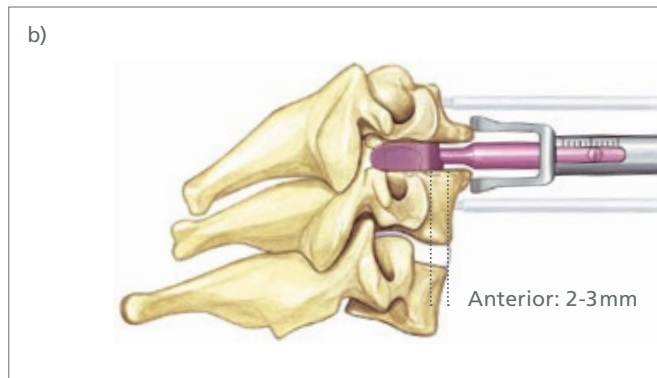


3. Trial Implants

Trial implants are utilized to define the appropriate implant size. The selected trial implant is centered at the midline of the medial-lateral diameter of the vertebral body. Maximum endplate coverage is recommended for optimal stress distribution. Three different heights are available for appropriate height restoration. Note: Segmental distraction should be released when measuring the appropriate implant height. Overdistraction should be avoided and can be controlled fluoroscopically.



By the use of the depth stop, an optimal insertion depth of about 1-2mm inside the posterior (a) and of about 2-3mm inside the anterior border (b) of the original vertebral body contour can be measured. This is verified under radiographic control. To avoid heterotopic ossification, it is not recommended to remove anterior osteophytes. As shown on the right anterior osteophytes will not be considered when measuring the depth (b).



4. Implant Insertion

The depth stop of the insertion instrument is adjusted to the depth measured on the trial implant.

The **DCI™** implant is slightly compressed and carefully introduced along the midline into the disc space under fluoroscopic control.

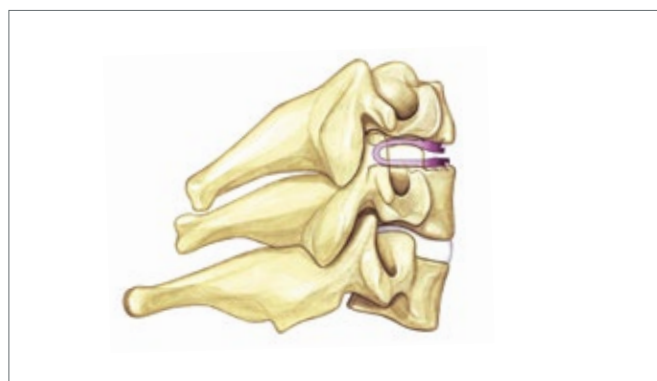
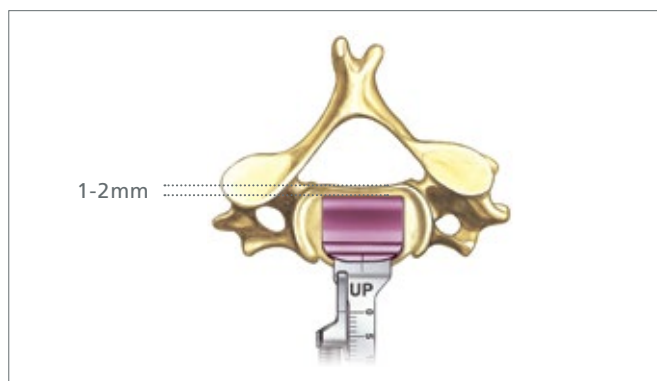
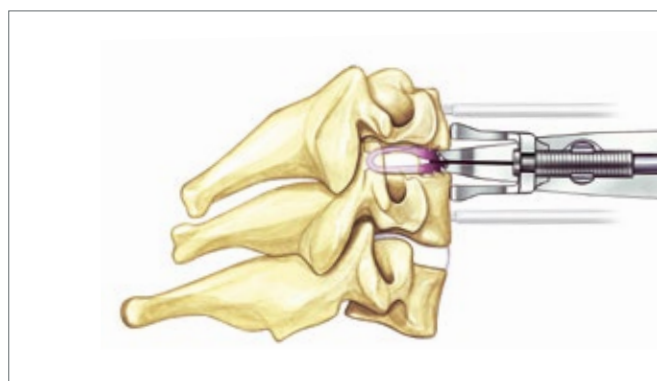
The implant should be positioned far posterior to fit the concavity of the inferior endplate of the superior vertebral body.

It is recommended not to remodel the endplate of the superior vertebral body.

Care has to be taken that the posterior edge of the implant has a 1-2mm separation from the dura.

It is important to position the implant 2-3mm inside the anterior border of the original vertebral body contour to provide optimal endplate accommodation and proper teeth engagement for primary stability.

Final positioning is confirmed fluoroscopically. The wound and skin is closed in the usual manner.



PATIENT CASES



Case 1

Female 42 Years, Designer

- **Symptoms:** Patient reported numbness in right hand and presented impaired reflexes at right biceps as well as a sensory deficit, right sided. Neck pain and very severe radicular pain.
- **MRI:** Disc degeneration and herniation at level C5-C6.
- **Diagnosis:** Herniated Nucleus Pulposus (HNP), medial, at level C5-C6.
- **Surgery:** Discectomy and implantation of *DCI*[™] implant size L6 (14mm, height 6mm) at level C5-C6.
- **Discharge:** No signs of myelopathy. Mild neck muscular spasms.
- **Follow-up at 12 months:** Patient is very satisfied with treatment. Full relief of neck and radicular pain.

Case 2:

Female 56 Years, Head of an Advertising Agency

- **Symptoms:** Slight dysfunction of fine motor skills and considerable sensory deficit. Severe neck and radicular pain, left sided.
- **MRI:** Herniated disc at C6-C7.
- **Diagnosis:** HNP at level of C6-C7.
- **Surgery:** Discectomy C6-C7 and implantation of *DCI™* implant size L5 (14mm, height 5mm) at C6-C7.
- **Discharge:** Complete recovery of motor skills and sensory deficit. Complete recovery of neck and radicular pain.
- **Follow-up at 24 months:** Patient is completely painfree.



PRODUCT INFORMATION

Sterilization Tray

CAC 00000



Instruments



Insertion Instrument CBT 20100

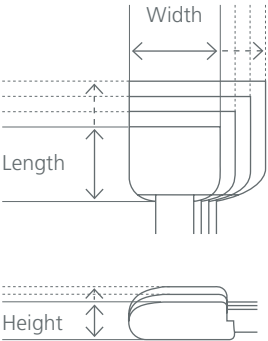






Inserter CBT 20000



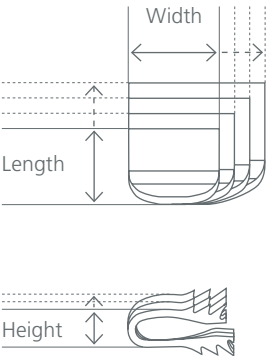
Trial Sleeve CBT 10001
Turning Knob CBT 10002

Trials



| Height | Size S  L: 10 mm W: 12 mm | Size M  L: 12 mm W: 14 mm | Size L  L: 14 mm W: 16 mm | Size XL  L: 16 mm W: 18 mm |
|--------|---|---|---|--|
| 7 mm | CBT 10127 | CBT 12147 | CBT 14167 | CBT 16187 |
| 6 mm | CBT 10126 | CBT 12146 | CBT 14166 | CBT 16186 |
| 5 mm | CBT 10125 | CBT 12145 | CBT 14165 | CBT 16185 |

DCI™ Dynamic Cervical Implant



| Height | Size S  L: 10 mm W: 12 mm | Size M  L: 12 mm W: 14 mm | Size L  L: 14 mm W: 16 mm | Size XL  L: 16 mm W: 18 mm |
|--------|--|--|--|---|
| 7 mm | CBI 10127 | CBI 12147 | CBI 14167 | CBI 16187 |
| 6 mm | CBI 10126 | CBI 12146 | CBI 14166 | CBI 16186 |
| 5 mm | CBI 10125 | CBI 12145 | CBI 14165 | CBI 16185 |



Material:
Wrought titanium 6-aluminum 4-vanadium alloy
according to ISO 5832-3.

The DCI™ implant is delivered sterile packed.



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the movement in spine care

Paradigm Spine GmbH
Eisenbahnstrasse 84
D-78573 Wurmlingen, Germany

Tel +49 (0) 7461 - 96 35 99-0
Fax +49 (0) 7461 - 96 35 99-20

info@paradigmspine.de
www.paradigmspine.com

Product not available in the USA