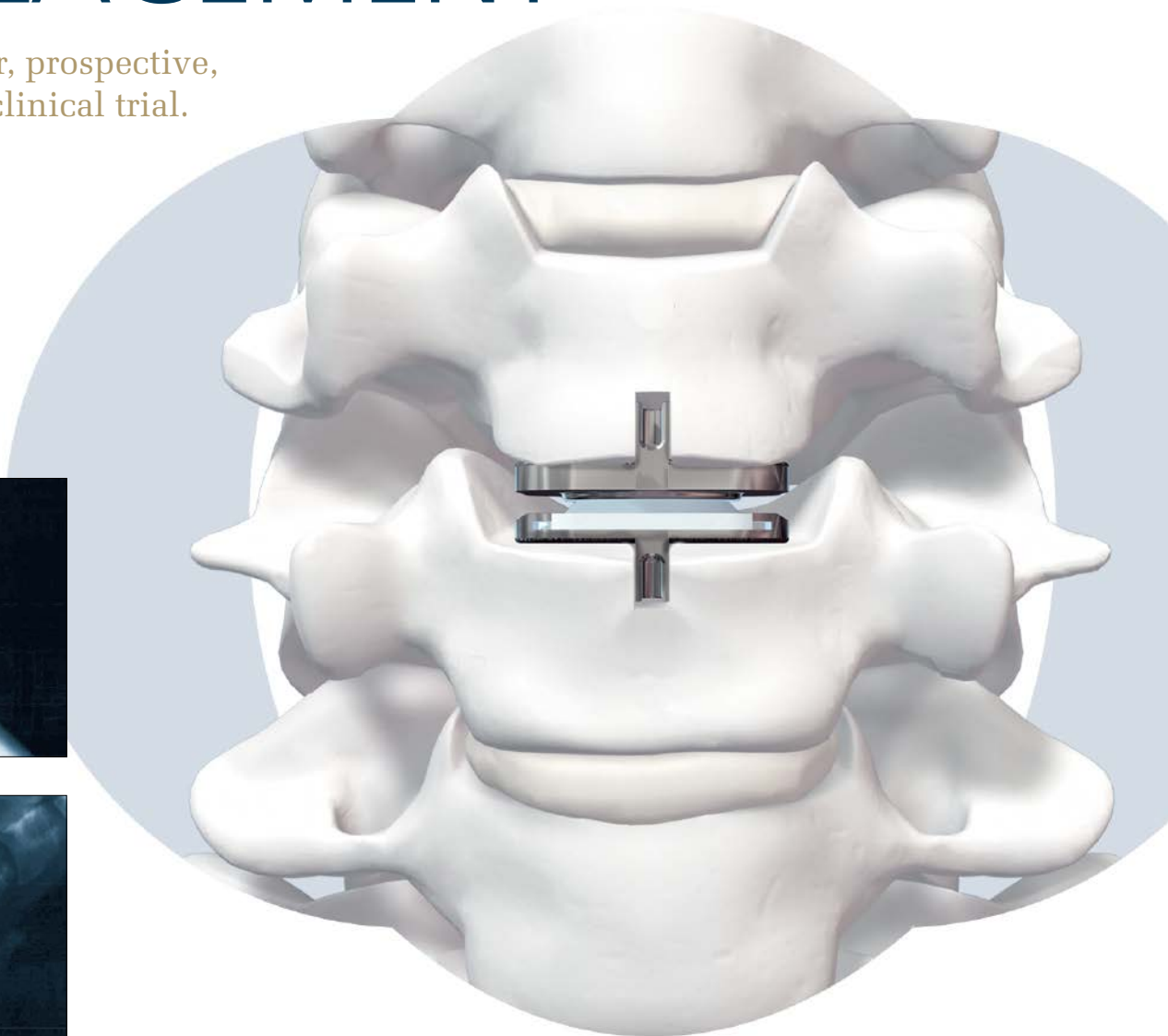


# PRODISC<sup>®</sup> C TOTAL DISC REPLACEMENT

A multicenter, prospective,  
randomized clinical trial.



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# CLINICAL STUDY

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## Study Objective

The study objective was to evaluate the safety and effectiveness of the PRODISC® C Total Disc Replacement compared to anterior cervical discectomy and fusion (ACDF) surgery for the treatment of discogenic pain associated with symptomatic cervical disc disease (SCDD) at one level between C3 and C7.



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## Study Design

The PRODISC C Total Disc Replacement was compared to an anterior cervical discectomy and fusion (ACDF) control consisting of an interbody fusion with cortical ring allograft bone and an anteriorly applied plating system.

PRODISC C Total Disc Replacement vs. ACDF:

- Multicenter, prospective, randomized trial
- 13 centers, 209 patients
  - 103 PRODISC C patients
  - 106 ACDF patients
- Single-level treatment (C3–C7)
- 1:1 randomization
- Follow-up at 6 weeks, and 3, 6, 12, 18 and 24 months



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**Inclusion Criteria:**

1. Symptomatic cervical disc disease (SCDD) in only one vertebral level between C3 and C7, defined as:
  - Neck or arm (radicular) pain; and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI or x-rays);
  - Herniated nucleus pulposus;
  - Spondylosis (defined by the presence of osteophytes); and/or
  - Loss of disc height
2. Age between 18 and 60 years
3. Unresponsive to nonoperative treatment for approximately six weeks or has the presence of progressive symptoms or signs of nerve root/spinal cord compression in the face of conservative treatment
4. NDI score greater than or equal to 15/50 (30% — Considered moderate disability)
5. Psychosocially, mentally and physically able to fully comply with this protocol including adhering to follow-up schedule and requirements and filling out forms
6. Signed informed consent

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**Exclusion Criteria:**

1. More than one vertebral level requiring treatment
2. Marked cervical instability on resting lateral or flexion/extension radiographs:
  - a. Translation > 3 mm and/or
  - b. > 11° of rotational difference to that of either adjacent level
3. Has a fused level adjacent to the level to be treated
4. Radiographic confirmation of severe facet joint disease or degeneration
5. Known allergy to cobalt, chromium, molybdenum, titanium or polyethylene
6. Clinically compromised vertebral bodies at the affected level(s) due to current or past trauma, e.g., by the radiographic appearance of fracture callus, malunion or nonunion
7. Prior surgery at the level to be treated
8. Severe spondylosis at the level to be treated as characterized by any of the following:
  - a. Bridging osteophytes;
  - b. A loss of disc height greater than 50%; or
  - c. Absence of motion (< 2°)
9. Neck or arm pain of unknown etiology
10. Osteoporosis: A screening questionnaire for osteoporosis, SCORE (Simple Calculated Osteoporosis Risk Estimation)<sup>1</sup>, will be used to screen patients who require a DEXA bone mineral density measurement. If DEXA is required, exclusion will be defined as a DEXA bone density measured T score  $\leq$  -2.5 (The World Health Organization definition of osteoporosis<sup>2</sup>)
11. Paget's disease, osteomalacia or any other metabolic bone disease (excluding osteoporosis, which is addressed above)
12. Severe diabetes mellitus requiring daily insulin management
13. Pregnant or interested in becoming pregnant in the next 3 years
14. Active infection—systemic or local
15. Taking medications or any drug known to potentially interfere with bone/soft tissue healing (e.g., steroids)
16. Rheumatoid arthritis or other autoimmune disease
17. Systemic disease, including AIDS, HIV, hepatitis
18. Active malignancy: A patient with a history of any invasive malignancy (except non-melanoma skin cancer), unless he/she has been treated with curative intent and there have been no clinical signs or symptoms of the malignancy for at least 5 years

1. Lydick E, Cook K, Turpin J, et al. Development and validation of a simple questionnaire to facilitate identification of women likely to have low bone density. *Am J Man Care* 1998; 4:37-48.

2. The WHO Study Group: Assessment of fracture risk and its application to screening for postmenopausal osteoporosis. Geneva, World Health Organization, 1994.

# PATIENT DEMOGRAPHICS AND INTRAOPERATIVE DATA

## Patient Demographics

Patient demographics were statistically similar for both the ACDF and PRODISC C groups.

Patients	ACDF	PRODISC C
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Patients	106	103
Follow-up rate at 24 months	94.8%	98.0%

## Demographics

Male	46.2%	44.7%
Female	53.8%	55.3%
Mean age (years)	43.5	42.1
Mean BMI (kg/m <sup>2</sup> )	27.3	26.4

## Treated Level

C3/C4	0.9%	2.9%
C4/C5	5.7%	9.7%
C5/C6	57.5%	56.3%
C6/C7	35.8%	31.1%

## Intraoperative Data

- Mean hospital stay and intraoperative complications were similar for both the ACDF and PRODISC C groups.
- Differences in mean operative time and mean blood loss were statistically significant, but may not be clinically significant.

Intraoperative Data	ACDF	PRODISC C
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Mean operative time (min)	98.7	107.2 *
Mean estimated blood loss (cc)	63.5	83.5 *
Length of hospital stay (days)	1.3	1.4
Intraoperative complications	0	2

\* Statistically significant difference (p < 0.05)

**Note:** For complete PRODISC C IDE study results, please see the Summary of Safety and Effectiveness Data at [www.fda.gov](http://www.fda.gov).

# CLINICAL RESULTS

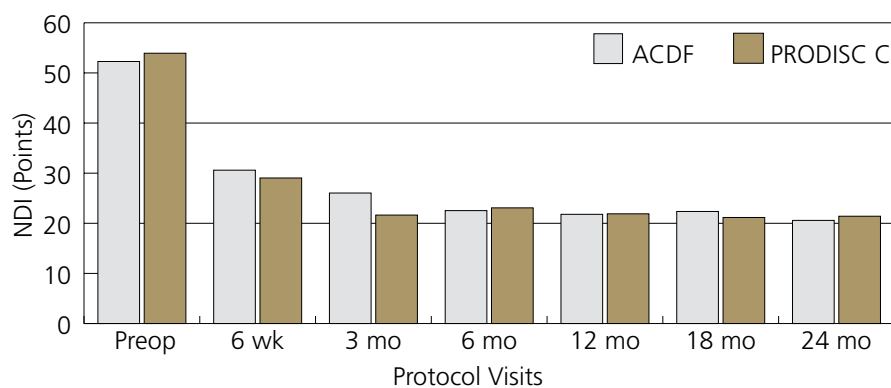
## Neck Disability Index (NDI)

- Both groups demonstrated a statistically significant improvement in NDI scores from baseline to 24 months ( $p < 0.05$ ).
- 84.9% of PRODISC C patients demonstrated clinically significant improvement<sup>†</sup> in NDI compared to 85.9% of ACDF patients at the 24-month timepoint.

Neck Disability Index	ACDF	PRODISC C
Mean preoperative score	52.3	53.9
Mean 24-month score	20.6	21.4
Patients with 20% improvement (24 mos.)	85.9%	84.9%
Patients with 15 point improvement (24 mos.)	78.3%	79.8%

<sup>†</sup>Clinically significant improvement in NDI is defined as  $\geq 20\%$  improvement

## Mean NDI Scores



## Neurological Success

Both groups showed high rates of neurological success at 24 months<sup>††</sup>.

	ACDF	PRODISC C
Neurological success <sup>††</sup>	88.0%	90.9%

<sup>††</sup>Neurological success defined as maintenance or improvement in motor sensory and reflexes

**Device Success**

At 24 months, there was a statistically significant difference in the incidence of revisions, removals, reoperations and supplemental fixation at the index level in favor of PRODISC C.\*

	<b>ACDF</b>	<b>PRODISC C</b>
Device Success <sup>†</sup>	91.5%	98.1% *

<sup>†</sup> No revisions, removals, reoperations or supplemental fixation at the index level  
 \* Statistically significant difference (p < 0.05 )

**Secondary Surgical Procedures**

- All secondary surgical procedures at the index level were recorded throughout the 24-month follow-up.
- The incidence of secondary surgical procedures was 1.9% for PRODISC C and 8.5% for ACDF, a statistically significant difference in favor of PRODISC C.\*

\* Statistically significant difference (p < 0.05)

<b>Treatment</b>	<b>Level</b>	<b>Reason</b>	<b>Secondary Procedure</b>
ACDF	C6–7C	Plate lift off, dysphasia	Plate removal
ACDF	C6–7C	Plate/allograft subsidence	Revision fusion
ACDF	C6–7C	Pain/pseudoarthrosis	Revision fusion
ACDF	C4–C5	Pain/pseudoarthrosis	Revision fusion
ACDF	C5–C6	Pain/pseudoarthrosis	Posterior supplemental fixation
ACDF	C6–7C	Pain/pseudoarthrosis	Posterior supplemental fixation
ACDF	C6–7C	Pain/pseudoarthrosis	Posterior supplemental fixation
ACDF	C6–7C	Foraminal stenosis	Laminectomy, foraminotomy
ACDF	C5–C6	Adjacent level disease	Plate removal, adjacent level fusion at C6–C7
PRODISC C	C4–C5	Arm/neck pain	Implant removal, fusion
PRODISC C	C4–C5	Neck pain	Implant removal, fusion

**Implant- and Implantation-Related Adverse Events**

The incidence of implant- and implantation-related adverse events was low for both treatments groups.

	<b>ACDF</b>	<b>PRODISC C</b>
Absence of implant/implantation-related adverse events	93.4%	97.1%

**Radiological Assessment**

All patients in the study were assessed based on data derived from plain films through 24 months. Patients with a secondary surgical procedure were excluded.

- No migration, subsidence or loss of disc height was observed in either treatment group.
- 90.2% of ACDF patients exhibited radiographic fusion.\*\*
- Bridging bone resulting in the loss of motion at the index level was observed in 3 PRODISC C patients.



PRODISC C 24-month extension



PRODISC C 24-month flexion



ACDF 24-month extension



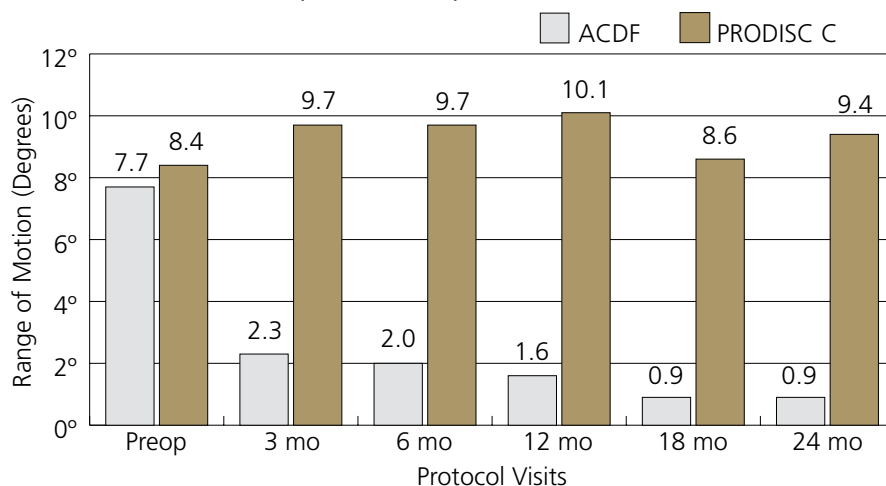
ACDF 24-month flexion

\*\*Radiographic fusion is defined as the presence of bridging bone and absence of radiolucencies

**Range of Motion (ROM)**

PRODISC C patients demonstrated a mean ROM of 9.4° at 24 months.

**Flexion/Extension ROM (Mean values)**

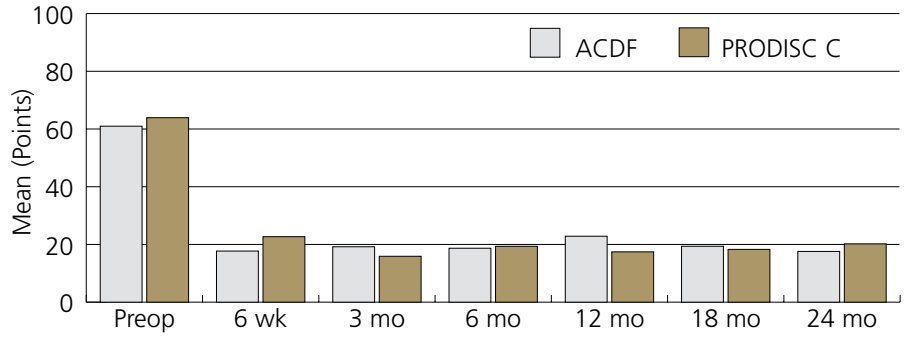




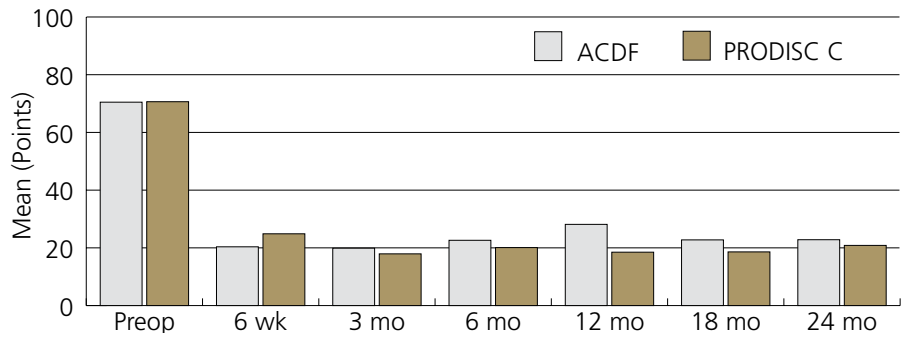
**VAS Pain Scales**

Both groups demonstrated a statistically significant improvement in VAS arm pain intensity and frequency and neck pain intensity and frequency scores from baseline to 24 months.

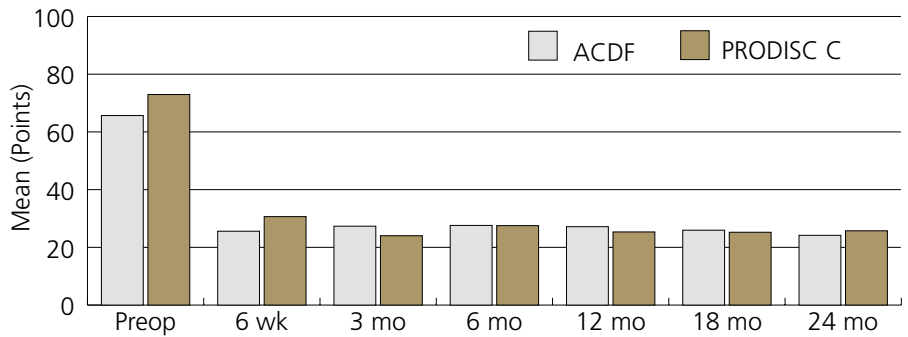
**Mean VAS Arm Pain Intensity Scores**



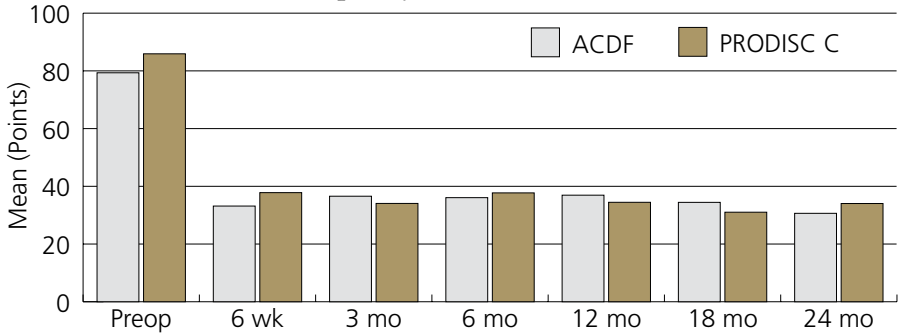
**Mean VAS Arm Pain Frequency Scores**



**Mean VAS Neck Pain Intensity Scores**

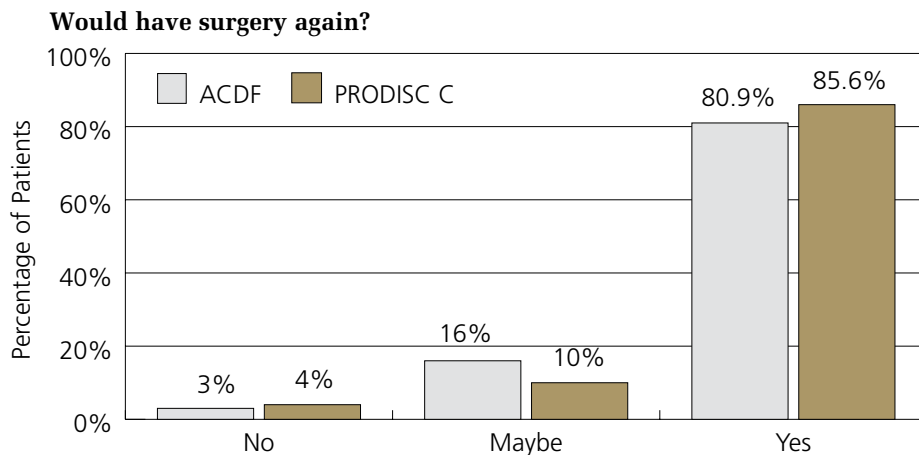


**Mean VAS Neck Pain Frequency Scores**



**Patient Satisfaction**

At 24 months, 85.6% of PRODISC C and 80.9% of ACDF patients indicated they would choose to have the same surgery again.



**VAS Satisfaction**

VAS satisfaction rates were high for both treatment groups.

<b>VAS Satisfaction at 24 months</b>	<b>ACDF</b>	<b>PRODISC C</b>
VAS satisfaction mean score	80.0	83.4
VAS satisfaction median score	92.9	96.0

# OVERALL SUCCESS AND CONCLUSIONS

## Overall Success

Overall success for the IDE clinical trial was calculated by determining the percentage of patients that met the success criteria for NDI, neurological, device success and absence of implant- or implantation-related adverse events.

- Patients had to demonstrate success in all four endpoints to be considered an overall success in the study.
- The results of the overall success analysis indicate that the PRODISC C Total Disc Replacement is non-inferior to ACDF.\*\*

	ACDF	PRODISC C
NDI $\geq$ 20% improvement from baseline	85.9%	84.9%
Neurological success	88.0%	90.9%
Absence of revisions, removals, reoperations, supplemental fixation (index)	91.5%	98.1% *
Absence of implant/implantation-related adverse events	93.4%	97.1%
Overall Success at 24 months	74.3%	77.2% **

\* Statistically significant difference ( $p < 0.05$ )

\*\*  $p=0.0017$  for a test of non-inferiority using a non-inferiority margin of 15%

## Conclusions

The PRODISC C Total Disc Replacement is a safe and effective treatment for intractable symptomatic cervical disc disease (SCDD) at one level between C3 and C7.

When compared to the standard of care, ACDF, the PRODISC C Total Disc Replacement was shown to provide the same pain relief and high patient satisfaction, with fewer reoperations.

PRODISC C Total Disc Replacement patients in the IDE study demonstrated:

- Significant improvement in pain and disability
- Fewer secondary procedures
- High rate of patient satisfaction

**Note: For more information regarding the PRODISC C IDE study, refer to the Summary of Safety and Effectiveness Data at [www.fda.gov](http://www.fda.gov).**



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