

Quality of Life Following Prestige LP Cervical Disc Arthroplasty in a Prospective Multicountry Study

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ABSTRACT

Background: To describe routine surgical practice using Prestige LP Cervical Disc (Prestige disc) and patient outcomes for degenerative cervical disc disease in a multicenter 2-year prospective, observational study.

Methods: Patient demographics and intraoperative data were collected; quality of life (QoL) (EQ-5D, EQ-VAS, and neck disability index), average disc height, and adverse events were assessed pre- and postoperatively at 3, 6, 12, and 24 months.

Results: One hundred and ninety-four patients were enrolled (190 patients implanted; female: 67%; mean age: 44.0 years; mean body mass index: 25.6). Disc herniation was the most frequent indication for cervical arthroplasty (80.5%). Thirty-seven percent of patients experienced pain for >1 year prior to baseline assessment. Mean procedure duration was 87.1 minutes, and mean blood loss was 43.8 mL. The majority (71.0%) of Prestige discs were implanted at level C5 to C6, while 16.3% of patients received implants at 2 levels. There was a significant improvement from baseline to 3, 6, 12, and 24 months of follow-up in all QoL assessments. After implantation, the mean disc height at the affected level increased by 0.19 from baseline (0.22) to 3 months (0.41) and remained constant up to 24 months ($P < .001$). Mean disc height of levels above and below the implant remained comparable at baseline and follow-up. A total of 63 adverse events (44 patients) was recorded, of which 7 (11.1%) were related to the Prestige disc, instrumentation, or procedure; 41 (65.1%) were unrelated; and 15 (23.8%) had an unknown relation.

Conclusions: In line with published findings, our study shows significant improvement in outcomes in the first 3 months after Prestige disc implantation with improvements maintained throughout the study.

Cervical Spine

Keywords: cervical spine, degenerative disc disease, arthroplasty, Prestige LP Cervical Disc, quality of life

INTRODUCTION

Traditional cervical surgical decompressions and fusions are the most common treatment option in patients with degenerative disc disease. Anterior cervical discectomy and fusion has been the standard therapy for many years. However, despite good treatment success rates, fusions can alter the normal kinematics of the spine (ie, limit the range of motion and cause subsequent development of adjacent segment degeneration) and can have related complications and pain.^{1–3} Total disc replacement using an artificial disc may therefore provide an alternative solution for patients suffering from degenerative disc disease to preserve motion in the affected level.⁴

This prospective observational study examined the use of the Prestige LP Cervical Disc system (Prestige disc) in patients with degenerative disc disease in central and eastern Europe and the Middle East.

MATERIALS AND METHODS

This was a prospective, multicountry, noninterventional, postmarketing study in patients scheduled for an implant of a Prestige disc for degenerative disc disease and fulfilling the indications according to the product description. The study was conducted in compliance with the study plan, local laws, and the Declaration of Helsinki.

The primary objective was the documentation of quality of life (QoL) before and after cervical disc

surgery using the Prestige disc. QoL was assessed using the EQ-5D and the neck disability index (NDI).

Secondary objectives were the documentation of duration of pain prior to enrollment; average disc height of the affected and adjacent disc levels; implantation data, such as size of cervical disc prosthesis, operation time, and blood loss; and heterotopic ossification (HO) throughout the course of the study. Tertiary objectives were collection of adverse events (AEs) and surgeons' perception throughout the course of the study, together with the economic considerations of hospital stay and time back to work.

Eligibility Criteria

To be eligible for the study, patients had to sign a study-specific data release form and agree to undergo surgery and evaluations according to hospital routine. Visits were scheduled at 3 months (visit date between implant and 4.5 months after surgery), 6 months (4.5–9 months), 12 months (9–18 months), and 24 months (more than 18 months postsurgery). Patients were excluded if they had not reached the age of legal consent according to local laws, fulfilled any contraindication according to the product description, had diabetes, had a body mass index greater than 35, had affected disc not between C3/C4 and C6/C7, had cervical instability, or were going to receive extensive decompression.

Clinical Evaluations

At enrollment (baseline), demographics, primary indication, general health status, affected disc level, and time of pain prior to enrollment were documented. In addition to these parameters, radiological evaluations were performed at enrollment and at follow-up visits together with documentation of concomitant medication and QoL, collected using the EQ-5D (<http://www.euroqol.org>),⁵ the NDI,⁶ and the visual analog scale (VAS) for neck and arm pain.

Investigator perception of the surgery outcome, classified as having poor, fair, good, very good, or excellent outcome, was collected at the follow-up visits. Information on the implantation device was recorded together with skin-skin time and blood loss at implantation. AEs were recorded throughout the course of the study.

Radiographic Evaluations

All radiological evaluations were performed by the participating site. Intervertebral disc space of the affected and adjacent disc levels was assessed in radiological images taken in the neutral position. The intervertebral disc height, measured as average disc height, was calculated as $[(A + B)/2]/H$, where A is the posterior intervertebral disc height, B is the anterior intervertebral disc height, and H is the anterior height of the upper vertebral body.⁷ Range of movement was documented by radiographic evaluation.

HO was documented postoperatively throughout the course of the study on a scale between 0 and 4: no HO present (0). HO detectable in front of the vertebral body but not in the anatomic intervertebral space (I). HO growing into the disc space with possible affection of the function of the prosthesis (II). bridging ossifications that still allow movement of the prosthesis (III), and complete fusion of the treated segment without movement in flexion or extension (IV).^{8,9}

STATISTICAL METHODS

Patients' demographics and characteristic categorical variables were analyzed by descriptive statistics. For continuous variables, mean values and standard deviations were calculated. For categorical variables, frequencies were calculated. The denominator for percentages was the number of nonmissing values. Relative frequencies were based on available observations (excluding missing values). For change from baseline analysis, when both baseline and follow-up data were known, the change from baseline was computed as follow-up assessment – baseline assessment. A 95% confidence interval was given, together with the descriptive statistics of continuous variables. *P* values for paired comparison for the changes from preoperative to the follow-up visits were generated using a paired *t* test.

RESULTS

Patient Demographics

One hundred and ninety-four patients with degenerative disc disease were enrolled in the study: 190 patients met the inclusion criteria, and 148 (77.9%) patients completed the last study follow-up visit at 24 months after implant (Figure 1). Four

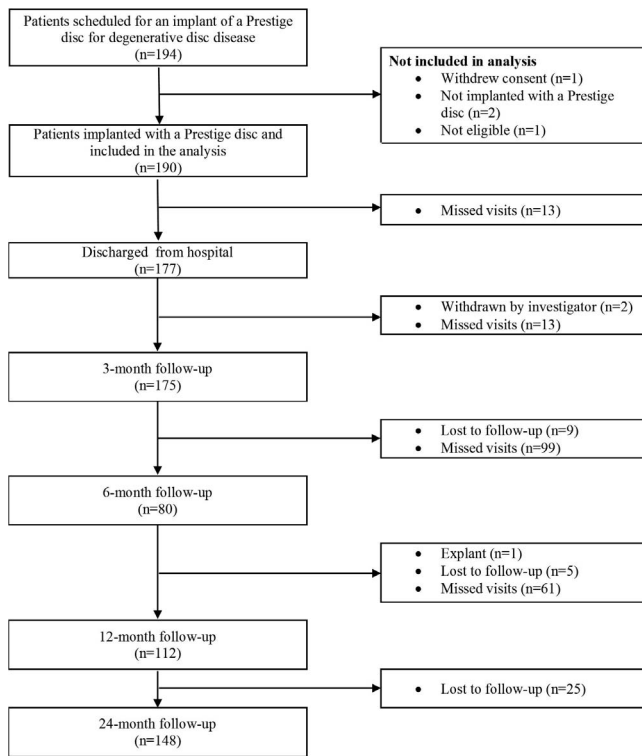


Figure 1. Study flowchart.

patients were excluded from the analysis for the following reasons: 1 patient withdrew consent, 2 patients did not receive the Prestige disc, and 1 patient violated the exclusion criterion (affected disc not between C3/C4 and C6/C7) and was excluded from the study by the investigator. The patients were enrolled at 15 sites in the Czech Republic (n = 44), Hungary (n = 13), Kuwait (n = 1), Poland (n = 86), Serbia (n = 11), Saudi Arabia (n = 11), and Slovakia (n = 28). The demographic and clinical characteristics of these patients are summarized in Table 1. Almost two-thirds (66.9%) of the 190 analyzed patients were female, with an average patient age of 43.9 ± 8.6 years (mean ± SD) and an average body mass index (BMI) of 25.6 ± 4.1

Table 1. Patient demographics and clinical characteristics before surgery.

Variable	Value, n = 190
Gender (male/female), no. (%)	63 (33.1)/127 (66.9)
Age, years, mean ± SD (range)	43.95 ± 8.6 (26–66)
BMI, mean ± SD (range)	25.6 ± 4.1 (17–37)
Duration of pain prior to baseline visit, no. (%)	
No pain	1 (0.5)
0–3 months prior to baseline	35 (18.4)
3–6 months prior to baseline	42 (22.1)
6–12 months prior to baseline	41 (21.6)
>12 months prior to baseline	71 (37.4)
Patients with previous cervical surgeries	11 (6.1)
Patients with concomitant diseases at baseline	134 (70.5)

Abbreviation: BMI, body mass index.

(Table 1). A substantial portion of patients (37.4%) reported pain duration of more than 1 year prior to baseline. One patient (0.5%) did not suffer from pain prior to baseline and was operated on based on radiological findings. Eleven patients (6.1%) had previous cervical surgery (cervical fusion procedures [n = 6], corpectomy [n = 1], transient stabilization [n = 1], and thyroidectomy [n = 3]). For the vast majority of the patients, the primary indication for cervical disc replacement was disc herniation (80.5%). Cervical spondylosis and osteophyte formation were the primary indication for disc replacement in 7.9% and 6.3% of the patients, respectively. Ten patients (5.3%) had other primary indications for disc replacement.

Seven patients did not meet all inclusion and exclusion criteria: 4 patients had diabetes, 1 patient had a BMI > 35, 1 patient had diabetes and BMI > 35, and 1 patient was receiving extensive decompression. These patients were included in the analysis, as diabetes and extensive decompression are not contraindications according to the Prestige disc instructions for use. The same holds true for BMI > 35 even though morbid obesity is a contraindication. These patients were therefore treated at the discretion of the treating surgeon.

One hundred and forty-eight patients (77.9%) completed the last study follow-up at 24 months (Figure 1). Of the 42 patients who did not complete the study, 39 patients were lost to follow-up, 2 patients were withdrawn from the study by the investigator after discharge as the patients did not return for their scheduled follow-ups, and 1 patient had the Prestige disc explanted 5 months after implantation due to recurrence of neck pain.

Surgery Data

For the 190 patients implanted, mean operative time was 87.1 minutes (SD: 45.2 minutes; range: 30 to 225 minutes; n = 190), and mean blood loss was 43.8 mL (SD: 64.4; range: 30 to 600 mL; n = 189). Further, 159 (83.7%) patients received implants in 1 level, and 31 (16.3%) received implants in 2 levels (total of 221 implants). Overall, including single- and double-level implants, C5/C6 was the level most frequently implanted (135 implants, 71.0%), followed by C6/C7 (50 implants, 26.3%), C4/C5 (33 implants, 17.4%), and C3/C4 (3 implants, 1.6%). Most patients with single-level implants were implanted in C5/C6 (104 patients, 54.8%) followed by C6/C7 (37 patients, 19.5%), C4/C5 (16 patients,

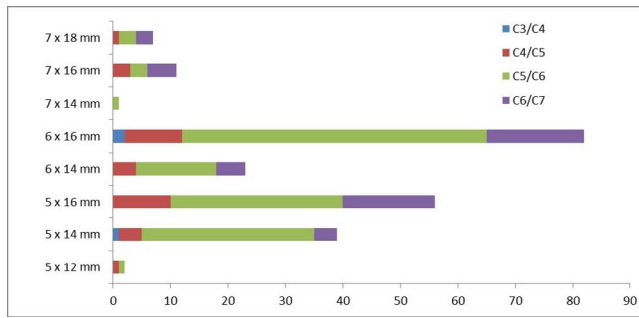


Figure 2. Number of Prestige discs implanted by size and implanted level (n = 221).

8.4%), and C3/C4 (2 patients, 1.0%). Most patients with double level implants were implanted in C4/C5 + C5/C6 (17 patients, 9.0%), followed by C5/C6 + C6/C7 (50 patients, 6.8%) and C3/C4 + C5/C6 (1 patient, 0.5%).

Although the Prestige disc is available in 13 different sizes, only 8 different sizes were implanted (Figure 2). The size most frequently implanted was 6 × 16 mm (82 implants, 37.0%) followed by 5 × 16 mm (56 implants, 25.3%), 5 × 14 mm (39 implants, 17.6%), and 6 × 14 mm (23 implants, 10.4%). The remaining implant sizes were used in 9.5% of the implants (21 implants). According to the investigators, the surgery outcome was good, very good, or excellent for most of the cases (Figure 3). This percentage remained stable for all follow-up visits: 96.5% at 3 months, 92.5% at 6 months, 92.8% at 12 months, and 88.4% at 24 months. There were no cases of poor outcome reported.

Following surgery, the median time to discharge from hospital was 3.0 days, with a mean of 4.8 days (±12.9) and a range of 1 to 116 days (n = 177). There was a slight decrease in the percentage of patients working at the time of surgery compared to those returning to work after surgery (from 59.3% to 52.0%) with 76.7% of those working at baseline

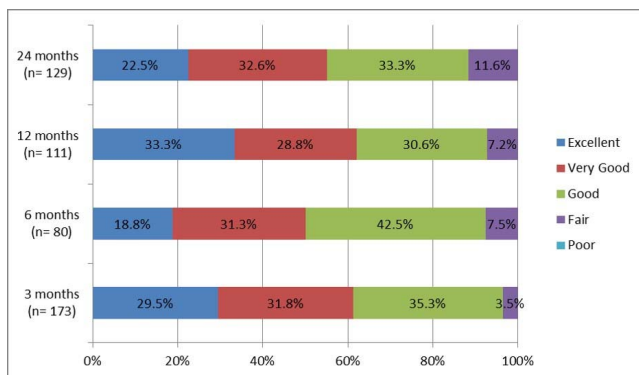


Figure 3. Investigator perception of the surgery outcome.

Table 2. Work status at baseline and return to work (n = 190).

Status	Value, no. (%)
Baseline (n = 189)	
Working	112 (59.3)
Not working	53 (28.0)
Retired	24 (12.7)
After surgery (n = 175), all patients	
Patient returned to work	91 (52.0)
Patient did not return to work	55 (31.4)
Not applicable	29 (16.6)

Abbreviation: n, number of patients.

returning to work (Table 2). The median time to return to work for all patients was 90.5 days, with a mean of 114.3 days (±116.1) and a range of 10 to 844 days (n = 86).

Patient-Reported Outcomes: EQ-5D

Mean EQ-5D index at baseline was 0.59 (±0.22), and mean EQ-5D VAS was 51.7 (±19.5) (Table 3). At the 3-month follow-up, the values increased, respectively, to 0.78 (±0.16) and 72.9 (±18.1), resulting in a statistically significant increase (P < .001) of 0.20 (±0.24) points in EQ-5D index and 23.1 (±22.9) points in EQ-5D VAS. The statistically significant improvement in EQ-5D index and EQ-5D VAS was maintained up to the 24-month follow-up. At this visit, EQ-5D index and EQ-5D VAS increased by 0.17 (±0.26) and 18.6 (±24.6) points, respectively, compared to baseline (P < .001 for both values).

At 24 months, the proportion of patients reporting no health-related problems increased from the preoperative values in each of the 5 individual EQ-5D dimensions: mobility (67.2% versus 56.8%), self-care (70.4% versus 53.5%), usual activities (50.4% versus 15.5%), pain/discomfort (27.0% versus 2.6%), and anxiety/depression (58.7% versus 34.8%) (Figure 4). For each dimension, the improvement could be observed from the 3-month follow-up.

At the 3-month follow-up, 78.7% (137 yes/37 no) of the patients had EQ-5D minimal clinically important difference (MCID), predefined as an improvement of 0.08. This improvement remained constant at the follow-up visits: 76.3% (61/19) at 6 months, 68.2% (73/34) at 12 months, and 75.6% (96/31) at 24 months.

NDI

The mean NDI at baseline was 24.1 (±8.6), which was reduced by -11.2 (±10.4) to 13.2 (±8.9) at 3 months (Table 4). This reduction was maintained to

Table 3. EQ-5D index and EQ-5D visual analog scale (VAS), together with change from baseline (n = 190).^a

Variable	Visit				
	Baseline	3 mo	6 mo	12 mo	24 mo
EQ-5D index	0.59 ± 0.22 (155)	0.78 ± 0.16 (164)	0.77 ± 0.20 (78)	0.80 ± 0.19 (102)	0.76 ± 0.21 (123)
Change from baseline	—	0.20 ± 0.24 (132)	0.22 ± 0.27 (61)	0.22 ± 0.25 (84)	0.17 ± 0.26 (104)
P value	—	<.001	<.001	<.001	<.001
EQ-5D VAS	51.7 ± 19.5 (152)	72.9 ± 18.1 (164)	72.0 ± 22.3 (77)	74.3 ± 21.0 (102)	71.4 ± 21.6 (126)
Change from baseline	—	23.1 ± 22.9	22.4 ± 24.8	23.1 ± 24.3	18.6 ± 24.6
P value	—	<.001	<.001	<.001	<.001

Abbreviation: n, number of patients.
^aResults are written as mean ± SD (n).

the last follow-up at 24 months (−10.0 ± 10.5). The improvement in NDI between baseline and follow-up was statistically significant (*P* < .001) for all visits.

At the 3-month follow-up, 79.9% (131 yes/33 no) of the patients had NDI MCID, predefined as an improvement of 5 points in the NDI compared to baseline. This improvement reduced slightly at the follow-up visits: 73.1% (57/21) at 6 months, 69.9% (72/31) at 12 months, and 73.0% (92/34) at 24 months.

Radiographic Outcomes

The implant increased the average disc height at the affected level from 0.22 (±0.07) at baseline to 0.41 (±0.15) at the 3-month follow-up, a change of 0.19 (±0.17) (Table 5, Figure 5). The statistically significant improvement (*P* < .001) in average disc height was maintained to the 24-month follow-up. The average disc height of the levels above and below the implant remained comparable between baseline and follow-up visits. Device subsidence, defined as a decrease in average disc height at the affected level, was reported in 4.1% of patients and 4.8% of affected levels at 3 months and in 8.7% of patients and 6.5% of levels at 24 months (Table 6).

The percentage of patients without HO (grade 0) at the affected levels decreased over time following the 3-month follow-up. This was associated with the occurrence of HO grades III and IV at the 12- and 24-month follow-ups (Table 7).

AEs

Over the course of the study, 63 AEs were reported in 44 patients (23.1%). From these, 8 events were serious AE (7 patients, 3.7%), and 2 events were classified as serious adverse device effects (2 patients, 1.0%). Seven (11.1%) of the reported

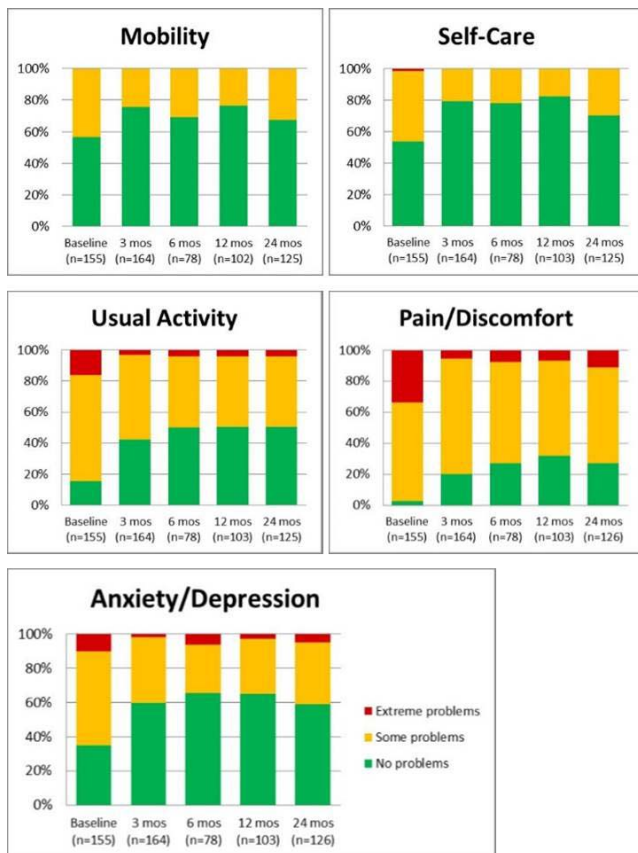


Figure 4. EQ-5D individual dimensions.

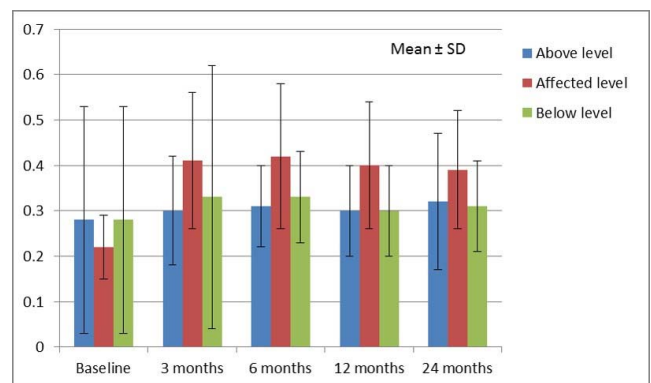


Figure 5. Intervertebral disc height measured as average disc height at affected and adjacent levels (mean ± SD). **P* value < .05, ***P* value < .001.

Table 4. Neck Disability Index score and change from baseline (n = 190).^a

Variable	Visit				
	Baseline	3 mo	6 mo	12 mo	24 mo
NDI	24.1 ± 8.6 (155)	13.2 ± 8.9 (164)	12.6 ± 10.2 (78)	12.3 ± 10.0 (103)	13.4 ± 10.3 (126)
Change from baseline	—	-11.2 ± 10.4 (132)	-11.5 ± 10.4 (61)	-12.0 ± 11.0 (85)	-10.0 ± 10.5 (107)
P value	—	<.001	<.001	<.001	<.001

Abbreviation: n, number of patients.
^aResults are written as mean ± SD (n).

AEs were related to the Prestige disc, instrumentation, or procedure, while 41 (65.1%) were not related, and 15 (23.8%) had an unknown relation.

Actions taken as a result of the AE are given in Table 8. For the event where a visit to the emergency room was needed, the event was described by the investigator as “lumbar pain, L5/S1 discopathy” and reported as not related to the Prestige disc, instrumentation, or procedure. One Prestige disc was explanted 5 months after implantation surgery due to the recurrence of symptoms, and the level was fused. The investigator reported that the event was not related to the Prestige disc, instrumentation, or procedure and also reported no problem with the device structure or position. At the last patient follow-up, 48 (77.4%) AEs were still ongoing, 10 (16.1%) were resolved, and 4 (6.5%) became a permanent condition. For 1 patient, no information on AE outcome was provided.

DISCUSSION

Implant of the Prestige disc in patients with degenerative disc disease resulted in a statistically significant improvement in QoL at 3 months, determined using the EQ-5D and NDI, and this was sustained up to the last follow-up visit at 24 months. The improvement in QoL was clinically relevant in 79.8% of patients, as defined as a 5-point improvement in NDI (MCID), and in more than

70% of patients, as defined as a 0.08-point improvement in EQ-5D. Furthermore 88.4% of the investigators reported a surgery outcome of good, very good, or excellent at 24 months, with no cases of poor outcome reported.

A statistically significant improvement in NDI of 10.0 points, equivalent to a clinical improvement of 20%, was reported at the 24-month follow-up. A US randomized study comparing Prestige disc with anterior cervical discectomy and fusion showed an improvement in NDI of 36.4% and 34.0%, respectively,¹ while two single-center studies in China and Singapore with the Prestige disc report NDI improvement of 13.8 points¹⁰ and 27.0%.¹¹ In central and eastern Europe, NDI improvements of 19.0%¹² and 7%¹³ are reported for the ProDisc-C (Synthes USA), with the results from the current study falling within the reported range. An NDI improvement of 48.1% is observed 3 to 4 years after surgery with the ProDisc-C.¹⁴

We report a statistically significant increase in EQ-5D index of 0.17 points and EQ-5D VAS of 18.6 points at the 24-month follow-up. Our data are within the range described previously: the SWISS spine group reported an increase of 0.40 point in EQ-5D index at the 24-month follow-up¹⁵ and an increase of 0.09 point in EQ-5D index and 19 points in EQ-5D Health Score for 7 patients undergoing cervical arthroplasty with ProDisc-C.¹⁶ For patients undergoing anterior cervical discectomy and fusion,

Table 5. Intervertebral disc measured as average disc height at affected and adjacent levels with change from baseline.^a

Variable	Visit				
	Baseline	3 mo	6 mo	12 mo	24 mo
Affected level (N = 221)	0.22 ± 0.07 (96)	0.41 ± 0.15 (98)	0.42 ± 0.16 (62)	0.40 ± 0.14 (64)	0.39 ± 0.13 (46)
Change from baseline	—	0.19 ± 0.17 (62)	0.19 ± 0.19 (41)	0.18 ± 0.15 (48)	0.16 ± 0.14 (31)
P value	—	<.001	<.001	<.001	<.001
Above level (n = 190)	0.28 ± 0.25 (111)	0.30 ± 0.12 (123)	0.31 ± 0.09 (62)	0.30 ± 0.10 (62)	0.32 ± 0.15 (89)
Change from baseline	—	-0.01 ± 0.29 (83)	0.01 ± 0.07 (37)	0.01 ± 0.07 (38)	-0.01 ± 0.34 (57)
P value	—	.788	.411	.344	.753
Below level (n = 190)	0.28 ± 0.25 (85)	0.33 ± 0.29 (90)	0.33 ± 0.10 (42)	0.30 ± 0.10 (42)	0.31 ± 0.10 (65)
Change from baseline	—	0.00 ± 0.32 (55)	0.05 ± 0.10 (24)	0.02 ± 0.08 (28)	-0.04 ± 0.37 (35)
P value	—	.946	.017	.146	.511

Abbreviations: n, number of patients; N, number of levels.
^aResults are written as mean ± SD (n).

Table 6. Device subsidence.^a

Device Subsidence	Visit			
	3 mo	6 mo	12 mo	24 mo
n available (missing)	62 (159)	41 (180)	48 (173)	31 (190)
Affected levels with device subsidence	3 (4.8)	4 (9.8)	1 (2.1)	2 (6.5)
Affected levels without device subsidence	59 (95.2)	37 (90.2)	47 (97.9)	29 (93.5)

Abbreviation: n, number of patients.
^aResults are written as n (% available).

a 0.14-point increase in EQ-5D has been reported 12 months after surgery.¹⁷

One of the goals of cervical arthroplasty is to restore normal disc height. In this study, there was an increase in disc height at the affected level at 3 months after surgery, and the disc height remained constant thereafter. Disc height of the levels above and below the implant remained unchanged pre- and postsurgery, in line with results reported in the literature.¹²

Device subsidence, defined as a decrease in average disc height at the affected level, was reported in 4.1% of patients and 4.8% of affected levels at 3 months and 8.7% of patients and 6.5% of affected levels at 24 months. Differences in the number of patients with subsidence among follow-up visits might be due to the fluctuations in the number of patients at each visit. We observed that HO was present in 44% of patients at the 24-month follow-up. This compares to the 8% to 16% incidence of HO reported after cervical arthroplasty^{10,18} but is lower than the 60% reported in a small retrospective study.¹⁹ HO does not have a negative influence on the clinical outcome, as range of motion was not restricted at 7-year follow-up following cervical arthroplasty in a prospective randomized controlled clinical trial.²⁰ Our findings are also in line with a recently published systematic literature review and meta-

Table 7. Heterotopic ossification at affected level (N = 221).^a

Heterotopic Ossification	Baseline	Visit			
		3 mo	6 mo	12 mo	24 mo
n available (missing)	72 (149)	168 (55)	75 (146)	88 (133)	107 (114)
Grade 0	56 (77.8)	157 (93.4)	69 (92.0)	72 (81.8)	60 (56.1)
Grade I	13 (18.1)	9 (5.4)	5 (6.7)	10 (11.4)	17 (15.9)
Grade II	3 (4.2)	1 (0.6)	1 (1.3)	2 (2.3)	9 (8.4)
Grade III	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.5)	13 (12.1)
Grade IV	0 (0.0)	1 (0.6)	0 (0.0)	0 (0.0)	8 (7.8)

Abbreviations: n, number of patients; N, number of levels.
^aResults are written as n (% available).

Table 8. Actions taken as a result of the adverse event.

Action Taken	No. (%), n = 63
Invasive intervention	14 (22.2) ^a
Prestige disc explanted	1 (1.6)
Emergency room visit	1 (1.6)
Medication change	15 (23.8)
Diagnostic testing	25 (39.7)
Other	12 (19.0)
No action taken	16 (25.4)

Abbreviation: n, number of patients.
^aPercentages sum up to more than 100%, as multiple answers were possible.

analysis in which the prevalence of HO after cervical artificial disc replacement within 1 to 2 years, 2 to 5 years, and 5 to 10 years of follow-up was 38.0%, 52.6%, and 53.6%, respectively, while the prevalence of severe HO was 10.9%, 22.2%, and 47.5%, respectively.²¹

On average, patients were discharged 4.8 days after surgery and returned to work 114 days after surgery. Time to discharge is greatly impacted by local practice and may be influenced by factors other than the patient’s clinical recovery. A single-site study in the Czech Republic reported a mean length of hospital stay of 3.7 days in patients undergoing cervical arthroplasty.¹⁵ Fifty-two percent of the patients returned to work after surgery, which is a slight decrease compared to the proportion working at baseline (59.3%). Return to work data should be interpreted with caution, however, as many factors may affect a patient’s work status, such as the patient’s motivation; social factors, including proximity to retirement; and the nature of the work performed.

Twenty-three percent of the patients experienced one or more AEs, of which 6 were related to the Prestige disc, instrumentation, or procedure. One case of Prestige disc explant occurred 5 months after the Prestige implant surgery. Other studies have reported a similar rate of AEs.^{11,18,20} This supports the safety of the Prestige disc and that it is without major neurological, subsidence, and reoperation issues at 2- to 7-year follow-up.

Our study has a few limitations. The study findings are limited by the fluctuations in the number of patients at each visit during follow-up, which reduced the statistical power of the comparisons. Therefore, the observed results should be interpreted with caution. The range of motion and VAS for neck and arm pain was not reported consistently in the study sites, which prevented analysis of these outcomes. However, other measurements of quality of life (EQ-5D and NDI)

showed that arthroplasty by Prestige was statistically and clinically improved.

CONCLUSION

This observational study describes the safety and effectiveness of arthroplasty in central and eastern Europe and the Middle East. Findings from this study are in line with published literature. QoL improvements, determined using the EQ-5D and NDI, were statistically and clinically significant 3 months after implantation, and these improvements were sustained to the last follow-up visit at 24 months with AE rates comparable to other total arthroplasty studies.

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REFERENCES

- Mummaneni PV, Burkus JK, Haid RW, Traynelis VC, Zdeblick TA. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. *J Neurosurg Spine*. 2007;6(3):198–209. <https://doi.org/10.3171/spi.2007.6.3.198>.
- Nabhan A, Ahlhelm F, Pitzen T, et al. Disc replacement using Pro-Disc C versus fusion: a prospective randomised and controlled radiographic and clinical study. *Eur Spine J*. 2007;16(3):423–430. <https://doi.org/10.1007/s00586-006-0226-5>.
- Silber JS, Anderson DG, Daffner SD, et al. Donor site morbidity after anterior iliac crest bone harvest for single-level anterior cervical discectomy and fusion. *Spine (Phila Pa 1976)*. 2003;28(2):134–139.
- König SA, Spetzger U. Clinical outcome of anterior cervical discectomy and fusion versus total disc replacement—a meta-analysis of 2532 cases. *Neurosurgery*. 2016;1(2).
- Shaw JW, Johnson JA, Coons SJ. US valuation of the EQ-5D health states: development and testing of the D1 valuation model. *Med Care*. 2005;43(3):203–220.
- Vernon H, Mior S. The neck disability index: a study of reliability and validity. *J Manipulative Physiol Ther*. 1991;14(7):409–415.
- Holte DC, O'Brien JP, Renton P. Anterior lumbar fusion using a hybrid interbody graft. a preliminary radiographic report. *Eur Spine J*. 1994;3(1):32–38. <https://doi.org/10.1007/BF02428314>.
- Mehren C, Suchomel P, Grochulla F, et al. Heterotopic ossification in total cervical artificial disc replacement. *Spine (Phila Pa 1976)*. 2006;31(24):2802–2806. <https://doi.org/10.1097/01.brs.0000245852.70594.d5>.
- Leung C, Casey AT, Goffin J, et al. Clinical significance of heterotopic ossification in cervical disc replacement: a prospective multicenter clinical trial. *Neurosurgery*. 2005;57(4):759–763, discussion 759–763.
- Chen F, Yang J, Ni B, Guo Q, Lu X, Xie N. Clinical and radiological follow-up of single-level Prestige LP cervical disc replacement. *Archives of Orthopaedic and Trauma Surgery*. 2013;133(4):473–480. <https://doi.org/10.1007/s00402-013-1689-6>.
- Peng CW, Yue WM, Basit A, et al. Intermediate results of the Prestige LP cervical disc replacement: clinical and radiological analysis with minimum two-year follow-up. *Spine (Phila Pa 1976)*. 2011;36(2):E105–E111. <https://doi.org/10.1097/BRS.0b013e3181d76f99>.
- Stulik J, Kryl J, Sebesta P, Vyskocil T, Krbec M, Trc T. ProDisc-C mobile replacement of an intervertebral disc. A prospective mono-centric two-year study. *Acta Chir Orthop Traumatol Cech*. 2008;75(4):253–261.
- Suchomel P, Jurak L, Benes V III, Brabec R, Bradac O, Elgawhary S. Clinical results and development of heterotopic ossification in total cervical disc replacement during a 4-year follow-up. *Eur Spine J*. 2010;19(2):307–315. <https://doi.org/10.1007/s00586-009-1259-3>.
- Hrabalek L, Vaverka M, Houdek M. Cervical disc arthroplasty (Prodisc-C): analysis of 3- to 4-year follow-up results. *Rozhl Chir*. 2009;88(11):634–641. [In Czech.]
- Schluessmann E, Aghayev E, Staub L, et al. SWISSpine: the case of a governmentally required HTA-registry for total disc arthroplasty: results of cervical disc prostheses. *Spine (Phila Pa 1976)*. 2010;35(24):E1397–E1405. <https://doi.org/10.1097/BRS.0b013e3181e0e871>.
- Hey HWD, Hong CC, Long AS, Hee HT. Is hybrid surgery of the cervical spine a good balance between fusion and arthroplasty? Pilot results from a single surgeon series. *Eur Spine J*. 2013;22(1):116–122. <https://doi.org/10.1007/s00586-012-2486-6>.
- Godil SS, Parker SL, Zuckerman SL, Mendenhall SK, McGirt M. Accurately measuring the quality and effectiveness of cervical spine surgery in registry efforts: determining the most valid and responsive instruments. *Spine J*. 2013;15(6):1203–1209. <https://doi.org/10.1016/j.spinee.2013.07.444>.
- Fabrizi AP, Schiabello L. Prospective clinical results of 1 level cervical arthroplasty with the prestige device: four year results. Paper presented at: International Society for the Advancement of Spine Surgery (ISSAS13); April 3–5, 2013; Vancouver, BC, Canada.
- Jin YJ, Park SB, Kim MJ, Kim KJ, Kim HJ. An analysis of heterotopic ossification in cervical disc arthroplasty: a novel morphologic classification of an ossified mass. *Spine J*. 2013;13(4):408–420. <https://doi.org/10.1016/j.spinee.2012.11.048>.
- Burkus JK, Traynelis VC, Haid RW Jr, Mummaneni PV. Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial: clinical article. *J Neurosurg Spine*. 2014;21(4):516–528. <https://doi.org/10.3171/2014.6.SPINE13996>.
- Kong L, Ma Q, Meng F, Cao J, Yu K, Shen Y. The prevalence of heterotopic ossification among patients after cervical artificial disc replacement: a systematic review and

meta-analysis. *Medicine (Baltimore)*. 2017;96(24):e7163. <https://doi.org/10.1097/MD.00000000000007163>.

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