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Mechanical Stability of the Prodisc-C Vivo Cervical Disc Arthroplasty: A Preliminary, Observational Study Using Radiostereometric Analysis

Miranda L. van Hooff, PhD[1,2], Petra J. C. Heesterbeek, PhD[1], and Maarten Spruit, MD, PhD[1]

Abstract

Study Design: Prospective cohort study.

Objective: To investigate the primary stability of the Prodisc-C Vivo cervical disc arthroplasty with regard to the adjacent cervical vertebrae using radiostereometric analysis (RSA), and to monitor its clinical performance.

Methods: Sixteen patients with degenerative cervical disc disease were included. RSA radiographs were obtained at the first postoperative day, at 6 weeks, 3 months, and 6 months postoperatively. Migration (translation [mm]) of the superior and inferior implant components were measured with model-based RSA, expressed along the 3 orthogonal axes, and calculated as total translation. Clinical outcomes were Neck Disability Index, numeric rating scales for neck and arm pain, Likert-type scales for satisfaction, and adverse events. Range of motion was reported as C2-C7 flexion-extension mobility (ROM).

Results: At final follow-up, no significant increase over time in median total translation was found. One inferior and 3 superior components subsided but were asymptomatic. ROM remained stable and clinical outcomes improved over time. Although 3 patients were unsatisfied and 3 adverse events occurred, this was not related to translation of the components.

Conclusions: On a group level, both components of the Prodisc-C Vivo cervical disc arthroplasty remained stable over time and below the clinical threshold of 1 mm. Individual outliers for translation were not clinically relevant and probably related to settling of the components into the vertebral endplates. RSA allowed us to perform a preliminary but accurate study on the micromotion of a new cervical disc replacement in a small sample size, without putting large numbers of patients at risk.

Keywords

spine, radiostereometric analysis, arthroplasty, implants, outcome

Introduction

Anterior cervical discectomy and fusion (ACDF) has been regarded the "gold standard" in surgical treatment of cervical degenerative disc disease (DDD). In recent years, growing evidence is available to consider cervical total disc replacement (CTDR) as an alternative.[1-3] Recently, a meta-analysis, showed superiority of CTDR (n = 1317) over ACDF (n = 1051) for the treatment of symptomatic cervical disc disease in terms of success in clinical performance, patient satisfaction, and superior adjacent segment degeneration (ASD).[4] These conclusions are confirmed by an expert review of long-term outcomes of disc arthroplasty for symptomatic single level cervical DDD.[3] Although few implant- and surgery-related serious adverse events have been mentioned and are favor for CTDR,[3,4] complications as implant migration and spontaneous fusion have been described.[2] CTDR aims to preserve segmental motion[2] and with that to prevent the incidence of ASD.[4,5] Cohort studies evaluating the long-term performance of different types of

[1] Sint Maartenskliniek, Nijmegen, the Netherlands
[2] Radboud University Medical Center, Nijmegen, the Netherlands

Corresponding Author:
Miranda L. van Hooff, Department of Research, Sint Maartenskliniek, P.O. Box 9011, 6500 GM Nijmegen, the Netherlands.
Email: m.vanhooff@maartenskliniek.nl

cervical disc prostheses indeed report maintenance of clinical cervical motion and functional outcome.[6-8]

The Prodisc-C Vivo is a third-generation CTDR after Prodisc-C and Prodisc-C nova. The ball-and-socket Prodisc-C design maintains cervical mobility, which is demonstrated in a 7-year follow-up randomized clinical trial comparing Prodisc-C and ACDF.[8] The Prodisc-C Vivo has a keel-less design and has 6 spikes on the superior and inferior surface intended to improve primary stability. As the footprints of the CTDR are smaller than the endplates of the vertebral bodies, a possible risk exists for implant subsidence into the adjacent vertebra. Subsidence is a commonly reported complication after CTDR, with an incidence of 3% to 10%.[9] This highlights the importance to investigate the primary stability as subsidence may limit motion of the CTDR or change kinematics (ie, center of rotation), and thus adversely affect clinical performance. Although radiostereometric analysis (RSA) is a highly accurate 3-dimensional measurement method to quantify micromotion between an implant and the host bone,[10] and recommended for the cervical spine,[11] RSA studies investigating the stability of implants in the cervical spine are scarce. Apart from the studies of Nabhan et al[1] and of Lind et al,[12] showing no migration in terms of translation, of respectively the first-generation Prodisc-C and the Bryan disc prosthesis, the authors are not aware of any publications that used accurate and precise measures to investigate micromotion of any CTDR and/or evaluated the primary stability and clinical performance of the Prodisc-C Vivo in particular.

The main purpose of this study was to investigate the primary stability, in terms of micromotion, of the Prodisc-C Vivo total disc replacement with regard to the adjacent vertebrae. Secondarily, to monitor its clinical performance in terms of cervical mobility, pain intensity, daily functioning, and incidence of adverse (device-related) events. Our hypothesis was that this implant remained stable over time.

Patients and Methods

Study Design

A single-center, single-surgeon prospective cohort study was performed between January 2014 and August 2017. The primary endpoint of the study was the stability of the Prodisc-C Vivo in the intervertebral space as measured with model-based radiostereometric analysis (MB-RSA) at 6 months follow-up assessment.

Ethics, Registration, and Potential Conflicts of Interest

The hospital's investigational review board and the medical ethical review board of Slotervaart (dossier NL456526.048.13) approved the study protocol. The study was conducted in compliance with the Declaration of Helsinki Good Clinical Practice guidelines, STROBE guideline, and ISO 16087:2013 for RSA. All patients were informed about the study and signed informed consent before inclusion. This study was funded by a restricted grant from AOFoundation. The sponsor did not take any part in the design, conduct, analysis, and interpretations stated in the final manuscript.

Patients

Eligible patients were adults with cervical disc disease requiring a cervical total disc replacement (CTDR). Inclusion criteria were single level C3-7 radiculopathy due to herniated disc, DDD, or spondylosis as confirmed by MRI; preserved motion at symptomatic level (confirmed by flexion/extension X-rays); failure of conservative treatment for at least 6 weeks; age $\geq$21 years. Exclusion criteria were kyphotic or congenital cervical deformity; loss of lordosis; multilevel spondylosis; disc height less than 50% of "normal" healthy disc; cervical trauma and instability; facet arthritis; infection; previous surgery at index level; osteoporosis; pregnancy (or plans to become pregnant during the study); body mass index $\geq$30 kg/m^2; tumor; and metastases.

Surgical Procedure

All patients received the Prodisc-C Vivo (2011; DePuy Synthes, Raynham, MA, USA) CTDR. The implant consists of 3 components; 2 cobalt chrome alloy (CoCrMo) endplates and an ultra-high-molecular-weight polyethylene (UHMWPE) inlay fixed on the inferior component. The articulation has an anatomical ball (inferior part) and socket (superior part) design. Three different heights are available (5/6/7 mm) and 6 different trapezoidal footprint sizes (M/MD/L/LD/XL/XLD). A single experienced orthopedic spine surgeon performed the surgery, using the appropriate guidance instruments and following the manufacturer's instructions. For each patient a standard left-sided anterior approach of the cervical spine was performed, the symptomatic disc was removed; the lateral parts of the annulus were preserved. The posterior longitudinal ligament was removed to have complete decompression of the spinal cord and nerve roots. After disc removal and endplate preparation trial implants were used to determine implant size. A C-arm was used to confirm a correct trial and implant position. The final implant was introduced en bloc while distracting the intervertebral space to prevent endplate violation by the spikes on the implant. After correct positioning, compression secured the primary implant position as the spikes are engaged into the endplates. Finally, 3 to 5 tantalum markers of 1 mm diameter (BAAT Medical Products BV, Hengelo, the Netherlands) were introduced into the adjacent upper and lower vertebral bodies (Figure 1). After surgery, all patients returned to normal activity within 6 weeks without using a collar and no physiotherapy was indicated.

RSA and Phantom Study

MB-RSA measurements were performed with MB-RSA software (RSAcore, Leiden, the Netherlands) and according to the ISO guideline for RSA (ISO 16087:2013(E) 2013). Patients

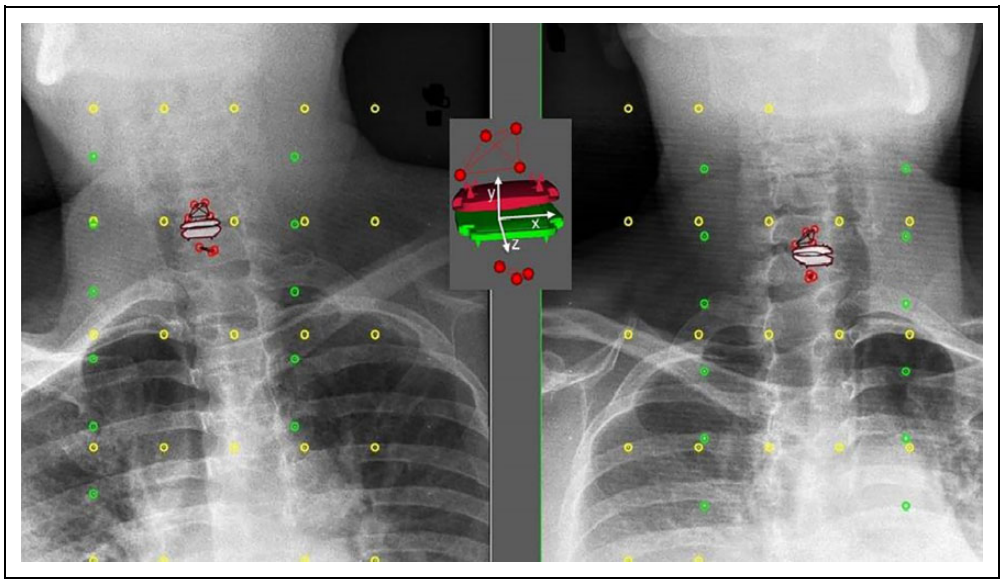

Figure 1. An analyzed model-based radiostereometric analysis (MB-RSA) image of a Prodisc-C Vivo cervical disc replacement and orientation of the longitudinal, transversal, and sagittal axes, including the positive directions for translation along the axes.

were lying in supine position with the cervical spine above the calibration cage (Carbon Box, Leiden, the Netherlands), placed under the table in a uniplanar setup. Prior to the start of the study, a phantom study was performed to determine measurement accuracy. Six pairs of RSA X-rays were compared. The accuracy of the RSA setup for both the components was $\leq$0.55 mm for translation along the 3 axes. Determining the accuracy for rotation was not feasible.

Primary Outcome: Implant Migration

The primary outcome with regard to implant stability was micromotion of the superior and inferior Prodisc-C Vivo component relative to the markers in the adjacent cervical bone segment. Patients were evaluated postoperatively, at 6 weeks ($\pm$1 week), at 3 months ($\pm$2 weeks), and at 6 months ($\pm$3 weeks) of follow-up. A 6-month follow-up was deemed appropriate to evaluate micromotion of the Prodisc-C Vivo, as subsidence is most frequent within the first 3 months after surgery.[13] Implant migration was expressed along the 3 orthogonal axes. The positive directions for migration (ie, translations) are left on transverse (*x*-) axis, cranial on longitudinal (*y*-) axis, and anterior on sagittal (*z*-) axis (Figure 1). *Total Translation (TT)* for inferior and superior component (respectively TT_{inf}, TT_{sup}) was calculated with the Pythagorean algorithm as $TT = \sqrt{(Tx^2 + Ty^2 + Tz^2)}$ as a summarizing outcome for translation along the 3 axes. As axial subsidence of implant components in the endplates might occur, separate analyses are performed for translation along the longitudinal (*Ty*) axis.

To assess the precision of RSA, double examinations were performed for 13 patients at the 6-week follow-up assessment and for 1 patient at 3-month follow up. Because of logistic reasons, these double examinations were not performed for 2 patients. Precision was calculated as the 95% confidence interval (1.96*standard deviation [SD]) around the mean migration between the 2 examinations. For both components a precision of $\leq$0.54 mm was found (Table 1).

Table 1. Precision of Double Examinations to Measure Migration (Translation; mm) of Inferior and Superior Components.

	Tx	*Ty*	*Tz*	*TT*
Superior	0.39	0.18	0.54	0.33
Inferior	0.26	0.19	0.38	0.19

Secondary Clinical Outcomes

Patient-reported outcome measures were used and completed preoperatively (baseline), at 6 weeks, at 3 months, and at 6 months of follow up. Numeric rating scale (NRS 0-10) was used for neck and arm pain in rest and during daily activities. To assess functional ability the Dutch validated Neck Disability Index (NDI, 0-100)[14] was used, with higher scores indicating more disability. At 3- and 6-month follow-up assessments, change in daily functioning compared with daily functioning before surgery was reported with a 7-point Likert-type scale (1 indicating "very much improved" and 7 indicating "very much worsened"). To indicate a relevant change in daily functioning at final follow-up, the scores were dichotomized ("improved" = scores 1-3; "worsened" = scores 4-7). Satisfaction with current neck symptoms was determined with the symptom well-being item of the Core Outcome Measures Index (COMI) neck[15]: "If you had to spend the rest of your life with the symptoms in your neck you have right now, how would you feel about it?" A 5-point Likert-type scale (1-5, with 1 indicating "very satisfied" and 5 "very unsatisfied") was used. To determine "satisfaction" at final follow-up, the scores

were dichotomized ("satisfied" = scores 1-2; "unsatisfied" scores = 3-5). The total flexion-extension mobility of the cervical spine (range of motion [ROM] C2 lower endplate to C7 upper endplate; degrees [°]) was assessed preoperatively and at 6-month follow-up with the vertebral corner assessment (VCA) tool.[16] This tool is based on the method as described by Frobin et al.[17,18] Using lateral X-rays, maximal flexion and extension angles were measured and the difference (ie, ROM) determined. Adverse (device and/or surgery-related) events (A[D]E) were recorded as well as all serious adverse (device-related) events (SA[D]E).

Sample Size

The following formula was used:

$$N = \frac{(Z_{\alpha/2})^2 \times s^2}{d^2},$$

where $Z = 1.96$ ($\alpha = 0.05$), standard deviation (s) is 2.0, and d is defined by the smallest clinically significant difference, which in this case is 1 mm. To detect a difference of 1 mm of micromotion of the Prodisc-C Vivo components at 6 months follow up a sample size of 16 patients was necessary, this includes an anticipated number of missing data because of marker occlusion.

Statistical Analysis

Descriptive statistics were used to provide an overview of patient characteristics. As all RSA and clinical outcome data was assessed as not normal distributed (Shapiro-Wilk test for normality), medians and ranges are presented for continuous parameters. Categorical parameters were described as numbers. To analyze migration and clinical performance over time the nonparametric Friedman analysis of variance test was used. The nonparametric Wilcoxon signed rank test was used to test stability in ROM between baseline and 6-month follow-up assessment. P values <.05 were considered statistically significant.

Results

Seventy patients were eligible for the study of whom 33 did not meet the inclusion criteria, 8 were excluded as they had previous surgery at the same level, in 9 patients the disc height was less than 50%, and 4 patients were excluded due to logistic reasons. Sixteen patients (9 female), median age 44 years (range 28-54 years), were included and completed the follow-up assessments (Table 2).

Table 2. Baseline Characteristics.

	Baseline (n = 16)
Demographics	
Age at time of surgery, years, median (range)	44 (28-54)
Gender (male:female) (n patients)	7:9
Index level (C5-C6:C6-C7) (n patients)	6:10
Characteristics Prodisc-C Vivo	
Size (M:MD:L:LD) (n patients)	5:5:5:1
Height, mm, (5:6) (n patients)	11:5

Implant Migration

Translation results of both Prodisc-C Vivo components are presented in Table 3. At 6-month follow-up, the median TT_{inf} was 0.51 mm (range 0.26-1.34 mm) and TT_{sup} 0.62 mm (range 0.03-1.14 mm). Median migration of both components remained ≤1 mm (Table 3; Figure 2); no significant increase in translation over time was found (inferior component Friedman's Q[2] = 4.67, $P = .10$; superior component Friedman's Q[2] = 0.67, $P = .72$). In Figure 3, the translations along the longitudinal (Ty) axis is shown per patient. The median migration along Ty is ≤1 mm and no significant increase in translation over time was found (inferior component Friedman's Q[2] = 1.16, $P = .56$; superior component Friedman's Q[2] = 2.00, $P = .37$).

Outliers occurred in 3 patients: 1 inferior and 3 superior components translated >1 mm over time (Figure 2). At 6-month follow-up, they were asymptomatic; no complaints and no adverse events occurred. Patients were "very satisfied" with their neck symptoms, reported to have "very much improved" in daily functioning compared with preoperative functioning, and NDI ranged from 0 to 16. Although in 1 patient (Prodisc-C Vivo at C6-C7) both components showed translation at all follow-up assessments (TT_{inf} 1.65, 1.14, and 1.34 mm; Table 3, patient A; Figure 2), the superior component remained stable around 1 mm (TT_{sup} 1.01, 1.08, and 1.01 mm). The inferior component showed translation along the Ty-axis at 6 weeks and 6 months of follow-up (−1.60 mm and −1.25 mm, respectively; Table 3, patient A; Figure 3). At 3-month follow-up, an asymptomatic subsidence of this component in the adjacent vertebra was noted in the patients' electronical medical record (Figure 4). To compare, Figure 5 shows an example of radiographs over time of a study patient in whom with MB-RSA stability of both components was shown. The superior component of a second patient showed translation at final follow-up ($TT_{sup} = 1.14$ mm; Tz axis 1.19, 0.81, 1.11, mm, respectively; Table 3 patient B). In a third patient, the superior component showed progressive, but asymptomatic, migration over time (TT_{sup} 0.24, 0.82, and 1.01 mm).

Secondary Clinical Outcomes

At 6-month follow-up, all clinical outcomes were significantly improved (Table 4). Although 14/15 were classified as "improved" in daily functioning and 12/15 were "satisfied" with their neck symptoms, for all outcomes the range of the different scores was large. A trend toward improvement of daily functioning (ΔNDI = −24; Table 4) and neck and arm pain is shown (Table 4). Three of 15 patients were unsatisfied with their neck symptoms of whom 1 experienced worsened daily functioning compared with preoperative daily functioning (NDI 40-62; NRS arm and neck pain in rest and during activities 4-8). In 3 other patients, 3 adverse events (not device-

Table 3. Migration (Median, Range [Min Max]; Mean [SD]) of Inferior and Superior Components of the Prodisc-C Vivo at the Follow-up Assessments.[a]

	Inferior Component			Superior Component		
	6 Weeks	3 Months	6 Months	6 Weeks	3 Months	6 Months
Transversal translation (*Tx*, mm)						
Median	0.03	−0.06	−0.03	−0.01	0.19	0.06
Min	−0.40	−0.31	−0.33	−0.42	−0.50	−0.27
Max	0.29	0.23	0.22	0.48	0.50	0.77
Mean (SD)	0.01 (0.27)	−0.04 (0.18)	−0.01 (0.16)	0.06 (0.28)	0.14 (0.23)	0.13 (0.28)
Longitudinal translation (*Ty*, mm)						
Median	−0.25	−0.25	−0.29	0.08	0.08	0.06
Min	−1.60[b]	−0.90	−1.25[b]	−0.10	−0.01	−0.05
Max	0.28	−0.06	0.26	0.64	0.52	0.59
Mean (SD)	−0.30 (0.39)	−0.31 (0.24)	−0.32 (0.32)	0.13 (0.17)	0.15 (0.15)	0.12 (0.17)
Sagittal translation (*Tz*, mm)						
Median	−0.03	0.08	0.17	0.14	0.04	0.51
Min	−0.58	−0.76	−0.55	−0.41	−0.53	−0.61
Max	0.61	0.87	0.54	1.19[c]	0.81	1.11[c]
Mean (SD)	0.02 (0.36)	0.06 (0.42)	0.10 (0.38)	0.21 (0.46)	0.14 (0.23)	0.64 (0.30)
Total translation (*TT*, mm)						
Median	0.45	0.48	0.51	0.41	0.42	0.62
Min	0.12	0.09	0.26	0.11	0.07	0.03
Max	1.65[b]	1.14[b]	1.34[b]	1.27	1.08	1.14[c]
Mean (SD)	0.54 (0.33)	0.54 (0.28)	0.57 (0.26)	0.52 (0.33)	0.46 (0.25)	0.64 (0.30)

[a]Positive values: *Tx* left, *Ty* cranial, *Tz* anterior. Condition numbers: median (range) for inferior component model 295 (180-1299) and for superior component model 386 (160-2192).
[b]Outlier (>1 mm): Patient A—translation (*TT*; *Ty*) of inferior component.
[c]Outlier (>1 mm): Patient B—translation (*TT*; *Tz*) of superior component.

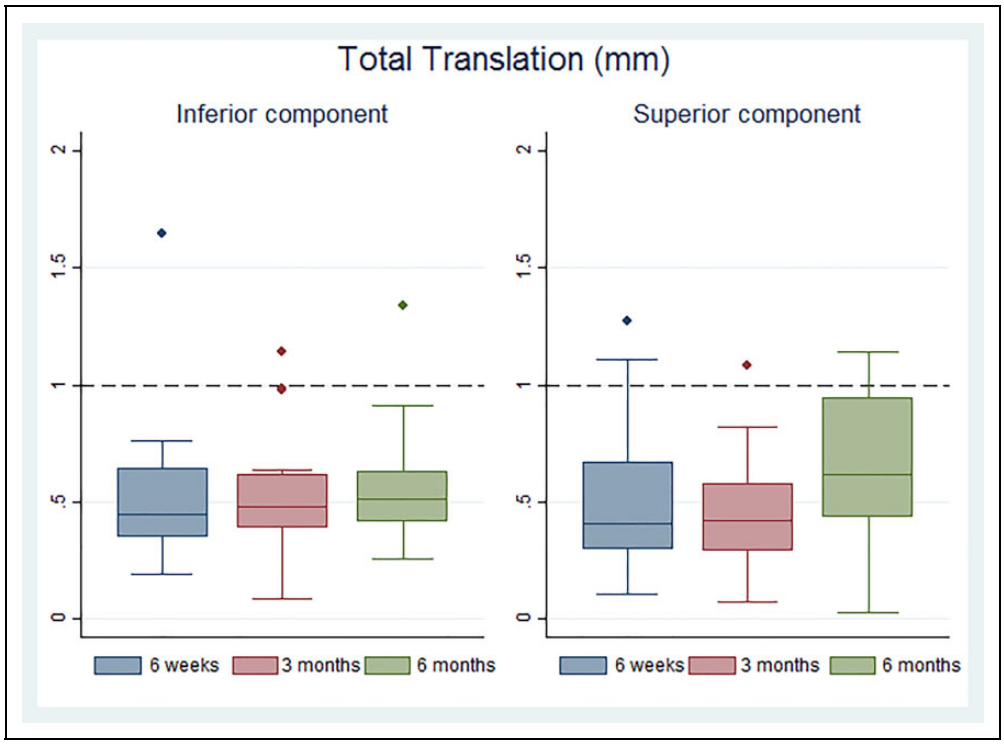

Figure 2. Migration (total translation [mm]) of the Prodisc-C Vivo components at the follow-up assessments. Top and bottom of boxplots: 25th and 75th percentiles. Horizontal line within box: median. Whiskers: lower and upper adjacent values. Dots: outliers. Horizontal black dashed line represents the 1 mm precision limit for translation.

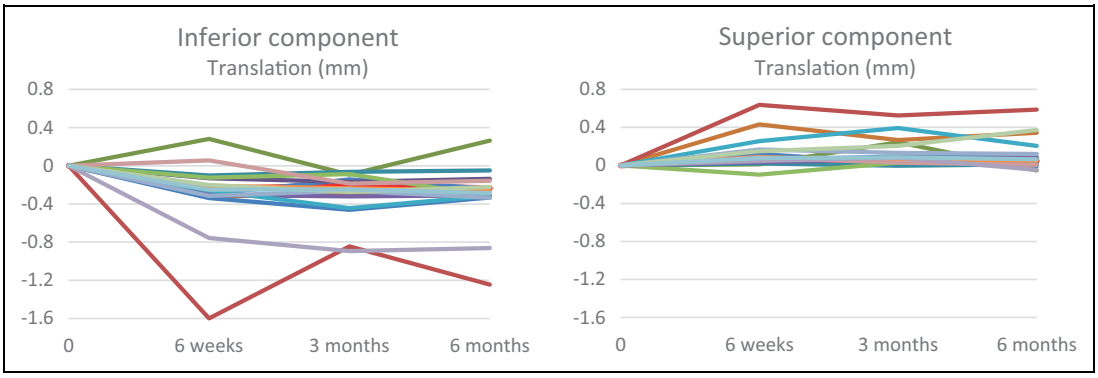

Figure 3. Translation (mm) along the longitudinal axis (*Ty*) per patient of the Prodisc-C Vivo components from postoperative assessment (0) until 6-month follow-up assessment.

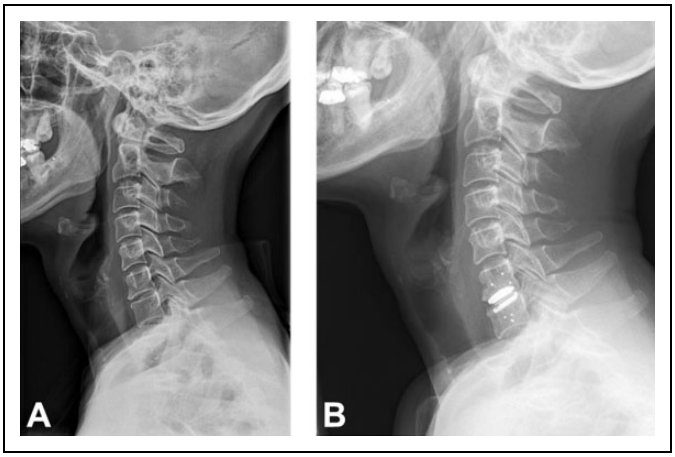

Figure 4. Preoperative radiograph (A) and a 3-month follow-up radiograph (B) showing subsidence of the inferior component into upper endplate of C7.

related) occurred and actions were taken to resolve these events (Table 5). Cervical mobility was maintained at final follow-up (ΔROM=0.0°; $Z = 1.19$, $P = .23$; Table 4).

Discussion

In this RSA study, the primary stability and clinical performance of the Prodisc-C Vivo CTDR in patients with degenerative cervical disc disease was investigated. Over 6 months, both components remained stable in terms of translation and below the clinical threshold of 1 mm while the cervical mobility was maintained. In the 2 RSA-studies we found, the stability of the Prodisc-C[1] and the Bryan disc prosthesis[12] was evaluated as an entire implant. At 6-month follow-up, the translation results of the Prodisc-C Vivo components along the 3 axes found in this study, were in line with the previously reported translations.

Reliability of RSA Measurements

Little is known about the reliability (ie, accuracy and precision) of RSA measurements in spine literature.[11] In a study by Hansen et al,[19] the authors examined the reliability of conventional marker-based and model-based RSA methods in the assessment of small-scale implants in hand surgery. They concluded that both RSA methods had low precision for rotation and should not be used for clinical assessment of implant rotation in small joint arthroplasty. Prior to the start of the present study, we performed a phantom study to determine the accuracy of the RSA setup. Although an accuracy of $\leq$1 mm appeared feasible for translations along the *x*-, *y*-, and *z*-axes ($\leq$0.55 mm), in line with Hansen et al,[19] an accuracy of $\leq 1^\circ$ for rotations was not feasible. As implant subsidence is of particular interest, that is, a translation along the *y*-axis, we focused on micromotion in terms of precise translation. A precision of $\leq$0.54 mm translation along the 3 axes was determined, which is comparable to those from RSA of total hip and knee arthroplasties.[20] Similar results for precision of translation were presented in a previous study with the first-generation Prodisc-C ($Tx = 0.45$ mm; $Ty = 0.30$ mm; $Tz = 0.65$ mm),[1] but no precision limits were presented in the study with the Bryan disc prosthesis.[12]

Clinical Relevance

Axial subsidence of the inferior implant component (ie, translation along the longitudinal [*Ty*] axis) in the endplate of the lower adjacent vertebrae is a commonly reported complication following CTDR and is usually associated with loss of anterior column height and/or endplate fracture.[21] Vertebral body preparation, an undersized implant and mismatch of the endplate with the footprint of the implant are regarded as the main causes of implant subsidence.[13,21] Because of the anatomical and keel-less design of the Prodsic-C Vivo, rigorous vertebral body preparation such as for a keel is not required, which theoretically minimizes the potential risk of postoperative implant subsidence. No significant increase in total translation of both components or more specifically along the *y*-axis was shown over a 6-month period. In 3 individual patients, a significant but asymptomatic translation of 4 implant components was observed. A possible explanation is that the spikes of the implant in these patients are still settling within the endplates of the adjacent vertebrae.

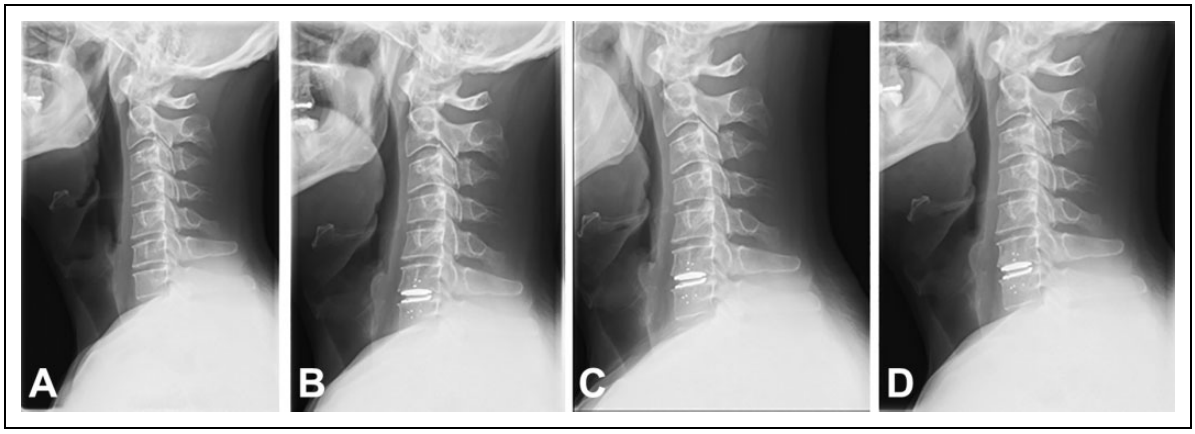

Figure 5. Example of a study patient showing preoperative (A), 6-week (B), 3-month (C), and 6-month (D) follow-up lateral radiographs of both Prodisc-C Vivo components.

Table 4. Clinical Performance.[a]

	Baseline	6-Week FU	3-Month FU	6-Month FU	Δ	H_0 Test
Functional status and pain intensity (n missing)	(2)	(1)	—	(1)	(2)	
NDI, median (range)	43 (14-82)	40 (2-64)	23 (0-62)	18 (0-62)	−24	$Q(3) = 43.24$, $P < .001$
NRS neck pain in rest, median (range)	6 (1-10)	2 (0-8)	1 (0-8)	1 (0-7)	−4	$Q(3) = 29.41$, $P = .003$
NRS neck pain neck during activities, median (range)	7 (3-10)	3 (0-9)	2 (0-9)	2 (0-8)	−5	$Q(3) = 34.38$, $P < .001$
NRS arm pain in rest, median (range)	6 (1-9)	0 (0-9)	0 (0-9)	0 (0-7)	−4	$Q(3) = 24.17$, $P = .02$
NRS arm pain during activities, median (range)	8 (1-10)	1 (0-8)	1 (0-10)	1 (0-8)	−5	$Q(3) = 28.24$, $P = .01$
Satisfaction symptom well-being (n missing)		(1)	—	(1)		
1/2/3/4/5 (n patients)	—	8/1/1/3/2	9/4/—/2/1	8/4/1/1/1	—	
Satisfied/Unsatisfied (n patients)		9/6	13/3	12/3		—
Change daily functioning (n missing)		(1)	—	(1)		
1/2/3/4/5/6/7 (n patients)	—	3/6/5/1/—/—/—	6/6/3/—/1/—/—	6/6/2/—/1/—/—	—	
Improved/Worsened (n patients)		14/1	15/1	14/1		—
Range of motion (n = 16)						
Maximal flexion-extension, degrees, median (range)	53.1 (35.9-68.4)	—	—	49.7 (23.4-71.3)	0.0	$Z = 1.19$, $P = .23$

Abbreviations: NDI, Neck Disability Index; NRS, numeric rating scale; FU follow-up; Δ change 6 months FU minus baseline; Q Friedman test; Z Wilcoxon signed rank test.
[a]Satisfied score 1-2; Unsatisfied score 3-5; Improved scores 1-3; Worsened scores 4-7.

Table 5. Type and Number of Adverse Events and Actions Taken.

Adverse Events	Action
n = 1 postoperative persistent pain neck and arms	Pain management after study closure
n = 1 postoperative hoarse	Speech therapy—much improved at 6-month follow-up
n = 1 at 3-month follow-up increasing headache	Further diagnostics after study closure

Overall, a trend toward satisfaction with experienced neck symptoms and improvement in self-reported functional and pain intensity scores is shown, which is in line with previous studies evaluating the clinical performance of CTDRs in patients with degenerative cervical disc disease.[1,4-8] Although at final follow-up, 3 patients were unsatisfied and in 3 patients adverse events occurred this was not related to translation of the CTDR. The total cervical flexion-extension mobility was maintained, which is in accordance with results presented in

previous studies.[6-8] To evaluate maintenance of segmental mobility[2] and possible kyphosis of the upper adjacent segment after Prodisc-C Vivo CTDR,[4,5,7,8] further studies have been initiated.

Some limitations of the present study should be mentioned. First, the study period was relatively long (2014-2017) due to a prolonged inclusion period. We used strict inclusion criteria to accurately and precisely evaluate the stability of the Prodisc-C Vivo in a homogeneous patient sample. Second, the sample size in the present study was small; a limitation inherent to RSA studies in general. The sample was sufficient and powered to study stability in terms of micromotion, but no firm conclusions can be drawn regarding the clinical outcomes. Third, to insert tantalum markers in an optimal position into the small vertebral bodies was a challenge. Sufficient markers (3-5) markers per vertebral body needed to be introduced for reliable RSA measurements (ISO 16 087:2013(E) 2013); the mean error of rigid body fitting (ME) values for marker stability were below the 0.35-mm threshold, and the translation values were accurate and precise. For some RSA measurements, after multiple checks, the condition numbers (CN; measure for marker distribution) were high (CN > 120). In small bones and with small implants an optimal position is difficult to achieve and high CNs are inevitable and accepted.[19] Fourth, the clinical threshold of 1 mm for translation of a CTDR seems arbitrary and up for discussion to determine a more relevant clinical threshold.

Conclusion

The median translational migration of both components of this third-generation CTDR remained below the 1-mm threshold. Outliers for translation of the implant components were not clinically relevant and are considered the result of settling of implant surface spikes into the vertebral endplates. RSA allowed us to perform a preliminary but accurate study on the micromotion of a new cervical disc replacement in a small sample size, without putting large numbers of patients at risk. Future longitudinal studies, adequately powered to evaluate prospectively collected clinical outcome data, are important to draw robust conclusions about the trends seen in this study.

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Author Contributions

The study was designed by MH, PH, and MS. Surgeries were performed by MS. Data collection and RSA analysis were performed by MH and PH. Statistical analysis was done by MH. MH, PH, and MS interpreted the data. All authors were involved in writing the manuscript; MH wrote the initial draft. MH, PH, and MS critically revised and approved the manuscript.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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ORCID iD

Miranda L. van Hooff, PhD https://orcid.org/0000-0001-5313-6436

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