Early Experiences of One-Level Total Disc Replacement (Prestige LP) in Japan: A Comparison of Short-Term Outcomes with Anterior Cervical Discectomy with Fusion

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Abstract:

Introduction: In Japan, cervical total disc replacement (TDR) was approved in 2017. However, because of its short history, no comparative study between cervical TDR and anterior cervical discectomy with fusion (ACDF) has been conducted in the country. Therefore, we examined and compared the surgical outcomes of TDR and ACDF for one-level cervical degenerative diseases.

Methods: In total, 50 patients who had received anterior surgeries for one-level cervical degenerative diseases were investigated. Among them, 25 underwent TDR (Prestige LP; Medtronic), whereas the other 25 patients underwent ACDF. ACDF samples were selected from cases conducted before the approval of TDR (–2017.9) and were retrospectively judged to be indicated for TDR. Before and at 1 year after surgery, clinical and radiological outcomes were evaluated.

Results: No significant differences in terms of patient demographics between the two groups were observed. A longer operative time was observed in the TDR group than in the ACDF group. Postoperatively, no differences in the Japanese Orthopaedic Association score for cervical myelopathy (C-JOA) score, neck pain visual analog scale, C2-7 angle, and C2-7 range of motion (ROM) were determined. TDR tended to show better neck disability index (NDI) scores postoperatively when compared with ACDF. The local angle at operative level was larger in ACDF. In TDR, the local ROMs were maintained postoperatively; however, in ACDF, the local ROM at the operative level was decreased, and the local ROMs at adjacent levels were increased postoperatively. In the TDR group, although heterotopic ossification was observed in 11 patients (44.0%), and anterior bone loss was identified in 14 patients (56.0%), these issues did not affect surgical outcomes.

Conclusions: Conclusively, no differences in terms of C-JOA score and neck pain between patients treated through TDR and ACDF were observed. However, a trend of better NDI scores was identified with TDR. While TDR maintained postoperative ROMs, ACDF showed an increase in the local ROMs at adjacent levels.

Keywords:

Cervical total disc replacement, anterior cervical discectomy with fusion, cervical degenerative diseases

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Introduction

Cervical degenerative diseases can result in neurological morbidity and reduced quality of life (QOL). Therefore, patients diagnosed with neurological deficits that improve insufficiently through conservative treatments require surgical treatments[1)]. Anterior cervical discectomy with fusion (ACDF) has been identified as one of the standard surgical treatments for cervical degenerative diseases, providing adequate decompression and stabilization of the spinal cord or nerve roots at the level of compression, with good long-term results being reported with this intervention[2,3)]. However, the nonbiological cervical fusion procedure places a burden on the adjacent intervertebral disc[4-6)], resulting in adjacent diseases at segments in medium- or long-term periods[7,8)].

Cervical total disc replacement (TDR) was developed mainly to prevent adjacent segment diseases (ASD) during cervical fusion procedures, such as ACDF, which is a mo-

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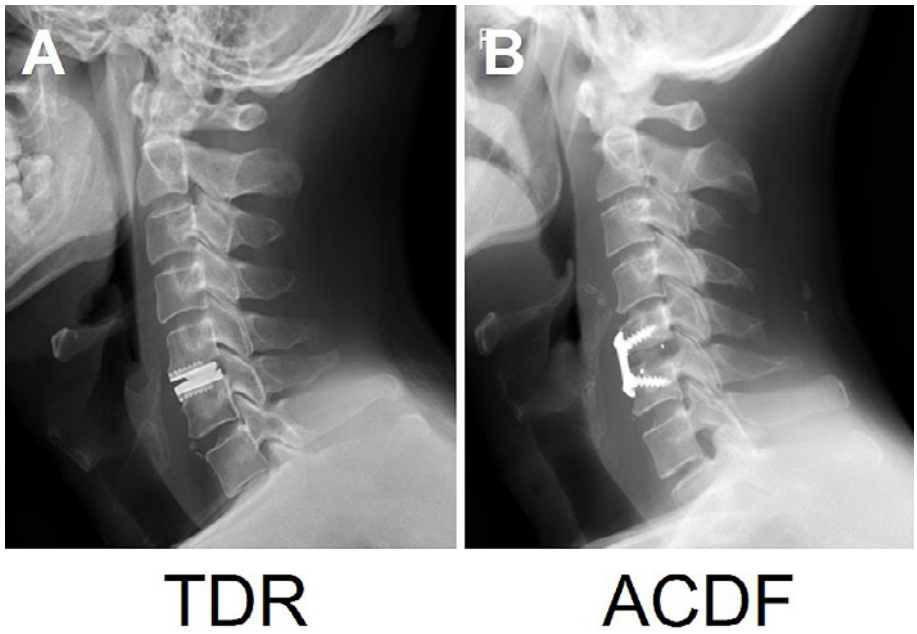

Figure 1. Postoperative X-ray images showing the cervical total disc arthroplasty (TDR) (A) and the anterior cervical discectomy with fusion (ACDF) (B).

tion preservation surgery where a mobile implant is placed at the intervertebral space after decompression[9,10]. It is also one of the standard treatments performed in more than 50 countries worldwide and was approved in Japan in 2017. The addition of new treatment methods for cervical spine diseases is therefore expected to enable more appropriate treatments for individual patients.

Both TDR and ACDF are proposed to be effective and have satisfactory clinical outcomes, especially in patients with short-segment diseases[11-13]. However, due to the short history of TDR in Japan, only one case series that investigated surgical outcomes of TDR has been reported[14]. Additionally, no study has directly compared these two surgical methods in the Japanese population. Therefore, we examined surgical outcomes of TDR and then compared these outcomes with a historical control of ACDF cases for treating one-level cervical degenerative diseases.

Materials and Methods

Materials

In total, 53 Japanese patients, who had received anterior cervical surgeries for one-level cervical degenerative diseases between January 2014 and July 2020, were enrolled in this study; 26 patients underwent TDR, whereas 27 underwent ACDF (Fig. 1, 2). After the approval of TDR in Japan (2017.10-), 26 TDR cases (Prestige LP; Medtronic) were conducted, of the 98 one-level anterior cervical surgery cases that reported at our institution, which was prospectively registered. TDR was indicated for cases with one-level cervical disc herniation or spondylosis, with no or mild degeneration, without apparent anatomical anomaly, instability, malalignment, and osteopenia. ACDF samples were selected from consecutive 93 presenting ACDF cases performed before the approval of TDR (2014.1-2017.9); then, these cases were retrospectively judged to be indicated for TDR. Two TDR supervising surgeons judged the cases based on patient's radiological images, neurological findings, and comorbidities. Consequently, 27 ACDF cases with concordant indications for TDR by both evaluators were selected. Exclusion criteria were as follows: presence of myelopathy or radiculopathy caused by neural compression at two or more levels, a history of a previous cervical spine surgery, and the presence of an infection or injury. This research has been approved by the institutional review board of the authors' affiliated institutions. Informed consent for publication was obtained from all patients.

Operative procedure

Cervical total disc replacement

TDR was conducted, following the standard Smith-Robinson's anterior cervical approach[2]. After exposure and confirmation of the appropriate vertebral levels, discectomy was performed. Osteophytes at the posterior part of vertebral bodies or the intervertebral foramen were subsequently removed using a high-speed drill and Kerrison rongeurs. Then, the posterior longitudinal ligament was totally or partially removed depending on pathology. The adjacent endplate was also preserved and paralleled like a letterbox using a high-speed drill. Afterward, a Prestige LP implant was placed into the disc according to the device guide, following postoperative external fixation with a soft collar for 2 weeks.

ACDF

ACDF was also performed, following the same approach, exposure, and discectomy as TDR. For ACDF, osteophytes

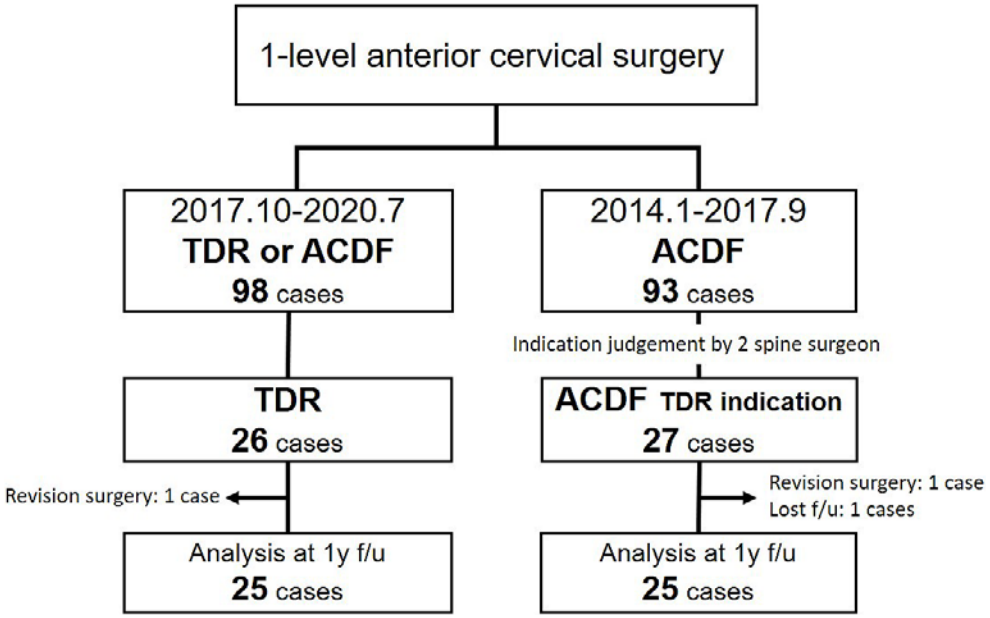

Figure 2. Procedure flowchart followed during this study for patients with one-level degenerative disease that underwent the anterior cervical surgery.

at the posterior part of vertebral bodies or intervertebral foramen were removed depending on pathology. After neural decompression, a pure polyetheretherketone (PEEK) or porous titanium-coated PEEK cage filled with artificial bones (hydroxyapatite/collagen composite) infused with a bone marrow aspirate was placed at the disc's space. A cervical plate was then affixed to the anterior surface of vertebral bodies, following postoperative external fixation with a hard collar for 1 month.

Outcome evaluation

Before and at 1 year after surgery, surgical outcomes were evaluated. Clinical results were assessed using the Japanese Orthopedic Association scoring system for cervical myelopathy (C-JOA score), neck pain visual analog scale (VAS), and neck disability index (NDI). To evaluate the recovery rate, the C-JOA score was calculated using Hirabayashi's method[15]. For the evaluation, lateral cervical spine radiographs of the neutral and functional positions were obtained before and at 1 year after surgery in all patients to measure the following: (1) the C2-7 angle; (2) local angle at the operative level; (3) the C2-7 range of motion (ROM); (4) local ROM at the operative level; and (5) local ROM at adjacent levels. Postoperative mechanical complications, implant migration after TDR, and cage subsidence after ACDF were both defined as subsidence of 1 mm or more. Additionally, in TDR, while postoperative heterotopic ossification (HO) was investigated according to McAfee classification[16], and anterior bone loss (ABL) was investigated according to Kieser classification[17].

Statistical analysis

Statistical analyses were conducted using the SPSS software version 24 (IBM Corp., Armonk, NY, USA). The Mann-Whitney U test was also used to compare continuous data between TDR and ACDF groups. Additionally, the Wilcoxon signed-rank test was used to compare obtained pre- and postoperative data. Moreover, the Kruskal-Wallis test was used to compare continuous data among HO and ABL subgroups in the TDR group. Finally, the chi-square test was used to compare the categorical data. $P<0.05$ was considered significant.

Results

Demographic data of patients in the TDR and ACDF groups

Of the 53 enrolled patients, 50 (94.3%; 41 men; 9 women; mean age, 47.3 years; 25 TDR; and 25 ACDF) completed the 1-year follow-up and were included for analyses (Fig. 2). One patient in the TDR group had implant dislocation and underwent ACDF 2 weeks after the initial surgery. One patient in the ACDF group also developed restenosis at the surgical level due to cage subsidence and underwent revisional ACDF 10 days after the initial surgery. Another patient in the ACDF group was lost to follow-up after 1 year. These patients were therefore excluded from the analysis. No significant differences in terms of patient age, gender, diagnosis, pathology, duration of symptoms, operative levels, C-JOA score, neck pain VAS, and NDI scores between the two groups were observed before surgery (Table 1). The preoperative C2-7 angle, the local angle at the operative level, the C2-7 ROM, the local ROM at the operative level, and local ROMs at the adjacent levels were significantly similar between the TDR and ACDF groups.

Table 1. Demographic Data of Patients in TDR and ACDF Groups.

	TDR (n=25)	ACDF (n=25)	*P*
Age at surgery (years)	47.9±10.3	46.8±9.8	0.816
Gender (male/female)	19:6	22:3	0.269
Diagnosis (cases)	Spondylosis: 6	Spondylosis: 10	0.225
	Disc herniation: 19	Disc herniation: 15	
Pathology (cases)	Myelopathy: 15	Myelopathy: 14	0.596
	Radiculopathy: 10	Radiculopathy: 10	
		Radiculomyelopathy: 1	
Duration of symptom (month)	17.2±18.1	16.1±24.4	0.456
Operative levels (cases)	C3/4: 2	C3/4: 1	0.640
	C4/5: 3	C4/5: 3	
	C5/6: 13	C5/6: 17	
	C6/7: 7	C6/7: 4	
Pre-C-JOA score (pts)	13.0±2.4	13.2±2.2	0.785
Pre-neck pain (VAS mm)	46.7±25.6	49.5±33.2	0.695
Pre-NDI (pts)	19.3±13.1	23.8±14.8	0.382
Pre-C2-7 angle (°)	8.8±9.9	8.3±11.6	0.992
Pre-local angle at op. level (°)	0.1±3.6	1.4±4.4	0.217
Pre-C2-7 ROM (°)	40.9±14.6	43.4±12.3	0.503
Pre-local ROM at op. level (°)	10.3±3.5	9.2±3.5	0.258
Pre-local ROM at upper level (°)	8.9±3.4	8.8±3.8	0.977
Pre-local ROM at lower level (°)	9.2±3.3	8.8±4.1	0.749

TDR, total disc replacement; *ACDF*, anterior cervical discectomy with fusion; *C-JOA*, Japanese Orthopedic Association for cervical myelopathy; *VAS*, visual analog scale; *NDI*, neck disability index; and *ROM*, range of motion

Table 2. Operative and Clinical Outcomes in TDR and ACDF Groups.

	TDR	ACDF	*P*
Operative time (min)	147.4±36.7	107.4±22.9	0.000*
Operative blood loss (ml)	23.6±38.2	13.5±12.1	0.504
Mechanical complication	Implant migration: 1	Cage subsidence: 4	0.157
Heterotopic ossification after TDR (case)	Grade 0: 14	-	-
	Grade 1: 4		
	Grade 2: 4		
	Grade 3: 3		
	Grade 4: 0		
Anterior bone loss after TDR (cases)	Grade 0: 11	-	-
	Grade 1: 7		
	Grade 2: 4		
	Grade 3: 2		
	Grade 4: 1		
Post-C-JOA score (pts)	15.9±1.1	16.0±0.8	0.675
(*P*: difference vs. preoperative. data)	(0.000*)	(0.000*)	
Recovery rate of C-JOA (%)	72.2±25.9	74.9±19.7	0.960
Post-neck pain (VAS)	26.0±28.4	28.8±25.4	0.504
(*P*: difference vs. preoperative. data)	(0.003*)	(0.005*)	
Post-NDI (pts)	6.9±8.0	10.8±10.1	0.096
(*P*: difference vs. preoperative. data)	(0.000*)	(0.001*)	

TDR, total disc replacement; *ACDF*, anterior cervical discectomy with fusion; *C-JOA*, Japanese Orthopedic Association for cervical myelopathy; *VAS*, visual analog scale; and * $P<0.05$.

Operative and clinical outcomes in TDR and ACDF groups

The operative and clinical outcomes of the TDR and ACDF groups are shown in Table 2. The operation time was noted to be significantly longer in the TDR group (147.4± 36.7 min) compared to the ACDF group (107.4±22.9 min; P =0.000). Moreover, no difference in intraoperative blood loss was observed. While one patient in the TDR group experi-

Table 3. Radiological Outcomes in TDR and ACDF Groups.

	TDR	ACDF	*P*
Post-C2-7 angle (°)	9.7±8.4	10.0±11.0	0.923
(*P*: difference vs. preoperative. data)	(0.594)	(0.211)	
△ C2-7 angle (°)	0.6±5.8	1.7±6.2	0.521
Post-local angle at op. level (°)	0.9±4.7	3.9±4.9	0.022*
(*P*: difference vs. preoperative. data)	(0.150)	(0.022*)	
△ local angle at op. level	−2.8±7.1	2.5±5.2	0.004*
Post-C2-7 ROM (°)	43.1±10.3	41.7±10.7	0.528
(*P*: difference vs. preoperative. data)	(0.386)	(0.647)	
△ C2-7 ROM (°)	2.2±12.2	−1.7±14.0	0.361
Post-local ROM at op. level (°)	8.9±3.7	0.6±1.0	0.000*
(*P*: difference vs. preoperative. data)	(0.083)	(0.000*)	
△ local ROM at op. level (°)	−1.4±3.8	−8.6±3.3	0.000*
Post-local ROM at upper level (°)	8.9±3.2	12.4±4.5	0.009*
(*P*: difference vs. preoperative. data)	(0.859)	(0.000*)	
△ local ROM at upper level (°)	−0.1±2.4	3.6±3.1	0.000*
Post-local ROM at lower level (°)	8.9±3.3	13.4±4.5	0.000*
(*P*: difference vs. preoperative. data)	(0.566)	(0.000*)	
△ local ROM at lower level (°)	−0.3±2.1	4.7±3.7	0.000*

TDR, total disc replacement; *ACDF*, anterior cervical discectomy with fusion; *ROM*, range of motion; △ , postoperative data–preoperative data; and * $P<0.05$.

enced implant migration, four patients in the ACDF group experienced cage subsidence after surgery. In the TDR group, HO was observed in 11 patients (44.0%; 4 in Grade 1, 4 in Grade 2, and 3 in Grade 3); ABL was observed in 14 patients (56.0%; 7 in Grade 1, 4 in Grade 2, 2 in Grade 3, and 1 in Grade 4). Postoperatively, the C-JOA score, neck pain VAS, and NDI levels were improved in both groups. Also, no differences in the postoperative C-JOA score (15.9 ±1.1 points in the TDR group and 16.0±0.8 points in the ACDF group), recovery rate of the C-JOA score (72.2%± 25.9% in the TDR group and 74.9%±19.7% in the ACDF group), and neck pain VAS (26.0±28.4 points in the TDR group and 28.8±25.4 points in the ACDF group) were observed. There was a trend of better NDI score in the TDR group (6.9±8.0 points) than in the ACDF group (10.8±10.1 points; *P*=0.096), although the difference was not statistically significant.

Radiological outcomes in TDR and ACDF groups

Radiological outcomes of the TDR and ACDF groups are shown in Table 3. The C2-7 angles did not change postoperatively in both groups, and no significant difference was observed between the two groups. The local angle at the operative level was smaller in the TDR group (0.9°±4.7°) than in the ACDF group (3.9°±4.9°; *P*=0.022), and that was maintained postoperatively in the TDR and increased in the ACDF. Results also showed that the C2-7 ROMs remained unchanged after surgery in both groups, and no significant difference existed between the two groups. Although postoperative local ROM at the operative level was maintained in the TDR group, it was markedly reduced in the ACDF group (0.6°±1.0°), and was smaller than that in the TDR group (8.9°±3.7°; *P*=0.000). Besides, although the postoperative local ROM at the upper level was maintained in the TDR group (8.9°±3.2°), it was increased in the ACDF group after surgery (12.4°±4.5°; *P*=0.000) and was larger than that in the TDR group (*P*=0.009) (Fig. 3). Similarly, the postoperative local ROM at the lower level did not differ from those of preoperative values obtained from the TDR group (8.9°±3.3°); however, it was increased in the ACDF group (13.4°±4.5°, *P*=0.000) and was larger than that in the TDR group (*P*=0.000) (Fig. 3).

HO and ABL in the TDR group

To investigate the impact of HO, we divided HO according to the McAfee classification into none (grade 0), mild (grade 1 and 2), and then severe (grade 3 and 4) subgroups within the TDR group, as previously reported[16], after which we compared them. No difference in the preoperative background, including postoperative clinical and radiological outcomes, was observed among the three subgroups (Table 4). The ABL was also divided into none (grade 0), mild (grade 1 and 2), and severe (grade 3 and 4) subgroups according to the Kieser classification within the TDR group, as previously reported[17], after which these groups were compared as well. Results showed no difference in terms of preoperative backgrounds, including patient's postoperative clinical and radiological outcomes among the three subgroups (Table 4).

Discussion

To date, several studies have investigated the surgical outcomes of TDR in western countries[11-13,18,19]. However, in Japan, TDR has been conducted mainly in authorized institutions since it was approved in 2017. Thus, there are limited cases that have been performed, and no comparative study

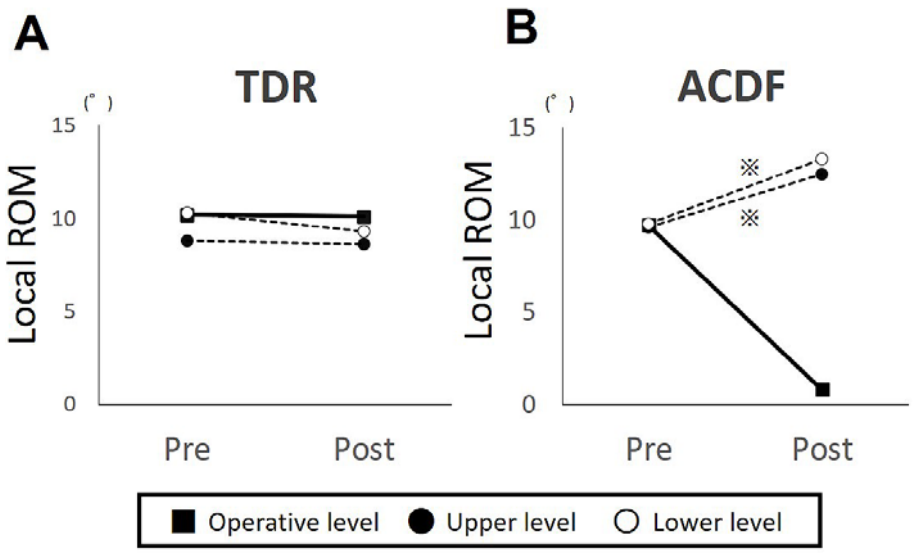

Figure 3. Postoperative changes in local range of motion (ROM) at the operative segment and upper and lower adjacent segments in cervical total disc arthroplasty (TDR) (A), and anterior cervical discectomy with fusion (ACDF) (B). ※ $P<0.05$.

Table 4. Heterotopic Ossification and Anterior Bone Loss in TDR Group.

	Heterotopic ossification				Anterior bone loss			
	None	Mild	Severe	*P*	None	Mild	Severe	*P*
No. of cases	14	8	3		11	11	3	
Age at surgery (years)	46.7±9.9	51.3±9.6	44.3±15.6	0.446	48.9±11.0	49.6±9.6	38.0±5.0	0.124
Gender (male/female)	11:3	5:3	3:0	0.407	8:3	9:2	2:1	0.814
Duration of symptom (month)	22.3±21.9	12.8±9.6	5.0±4.4	0.178	10.3±8.8	26.6±23.0	7.7±4.0	0.173
Pre-C-JOA score (pts)	13.5±2.4	13.6±1.3	9.5±2.6	0.072	13.1±3.0	13.2±2.1	12.0±1.7	0.302
Post-C-JOA score (pts)	15.9±1.2	16.1±0.9	15.0±0.9	0.290	16.0±0.9	15.8±1.2	15.3±1.3	0.583
Recovery rate of C-JOA (%)	71.0±30.8	75.0±21.4	70.2±18.3	0.952	73.0±28.7	72.2±26.9	69.4±17.3	0.845
Pre-neck pain (VAS mm)	51.0±22.8	35.9±27.7	51.7±36.2	0.454	44.8±27.9	47.7±23.2	50.0±34.6	0.936
Post-neck pain (VAS mm)	27.2±26.7	22.9±35.0	27.3±30.3	0.663	17.6±20.7	29.9±32.6	43.3±37.9	0.562
Pre-NDI (pts)	23.5±14.3	12.6±8.1	15.3±11.8	0.224	21.8±13.5	18.8±13.8	11.7±9.1	0.501
Post-NDI (pts)	8.0±9.1	4.3±6.2	8.0±7.2	0.355	8.0±9.7	4.3±5.2	11.7±8.4	0.257
Pre-C2-7 angle (°)	10.9±11.2	5.5±8.8	7.4±4.5	0.555	8.5±10.2	10.0±11.0	5.3±5.9	0.794
Post-C2-7 angle (°)	10.9±10.5	8.6±5.6	7.1±2.6	0.771	9.1±10.0	11.5±7.6	5.3±4.5	0.463
(*P*: difference vs. preoperative. data)	(0.937)	(0.441)	(0.785)		(0.646)	(0.756)	(1.000)	
Pre-local angle at op. level (°)	–0.3±4.1	0.8±2.6	–0.4±4.1	0.698	0.1±4.1	0.3±2.9	–1.0±5.0	0.832
Post-local angle at op. level (°)	0.8±5.3	2.5±3.9	–2.9±1.8	0.156	0.3±5.0	2.1±5.0	–1.3±1.5	0.482
(*P*: difference vs. preoperative. data)	(0.195)	(0.138)	(0.180)		(0.575)	(0.074)	(0.655)	
Pre-C2-7 ROM (°)	43.1±16.8	39.9±8.3	33.6±19.0	0.527	40.8±14.0	41.9±16.2	37.7±15.1	0.899
Post-C2-7 ROM (°)	42.8±11.4	43.3±10.5	44.2±5.8	0.756	44.3±13.3	42.0±7.9	43.0±7.8	0.858
(*P*: difference vs. preoperative. data)	(0.937)	(0.326)	(0.285)		(0.333)	(0.959)	(0.593)	
Pre-local ROM at op. level (°)	10.8±4.2	10.1±2.0	8.4±3.5	0.646	9.0±2.9	11.8±4.0	9.7±2.1	0.215
Post-local ROM at op. level (°)	9.8±3.0	8.8±4.1	4.8±4.3	0.153	9.1±5.2	9.1±2.1	7.3±2.1	0.552
(*P*: difference vs. preoperative. data)	(0.509)	(0.235)	(0.102)		(0.893)	(0.160)	(0.102)	

Heterotopic ossification: *None* grade 0, *Mild* grade 1 or 2, and *Severe* grade 3 or 4 according to the McAfee classification.

Anterior bone loss: *None* grade 0, *Mild* grade 1 or 2, and *Severe* grade 3 or 4 according to the Kieser classification.

TDR, total disc replacement; *C-JOA*, Japanese Orthopedic Association for cervical myelopathy; *VAS*, visual analog scale; *NDI*, neck disability index; and *ROM*, range of motion

on TDR and conventional ACDF in the Japanese population has been conducted. Two prostheses are currently available in clinical settings: the Mobi-C (Zimmer-Biomet) and Prestige LP (Medtronic). Since implants were developed and designed for western populations, it is important to investigate clinical results and complications in Japanese patients. Thus, this study gives the first report on clinical and radiological outcomes of metal-on-metal type implants (Prestige LP), af-

ter which we compared these with ACDF procedures previously conducted in our institutions.

The advantage of TDR is the prevention of ASD after fusion surgeries. Hilibrand AS *et al*. reported that symptomatic ASD after anterior fusion surgeries was 2.9% per year and 25.6% within 10 years, which is not a rare event[7]. Many previous studies had also shown that TDR prevented ASD[11-13,18-20] by decreasing postoperative biomechanical loads on adjacent discs[4-6,21]. Moreover, in randomized controlled trials comparing TDR (Prestige LP; Medtronic) and ACDF, the reoperation rate of TDR was reduced to 67% in one-level patients and 30% in two-level patients, compared with ACDF at a 7-year postoperative follow-up[22,23]. Since this study presented short-term outcomes of TDR and ACDF, no revision surgeries were conducted due to the ASD observed during the follow-up period. However, significant increases in ROMs at the upper and lower adjacent levels were observed after ACDF, which did not increase after TDR. Similarly, Dong L *et al*. previously reported that in a meta-analysis of randomized controlled trials, no difference in the rate of ASD within a 2-year follow-up period was observed, but as the follow-up period increased, records showed that the rate of ASD in TDR was significantly lower than that in ACDF[20]. Given these facts, even in this cohort, TDR is proposed to be able to reduce the rate of future ASD cases in the mid to long term.

Previous studies have reported that TDR is superior to ACDF in NDI score, which is an indicator of health-related-QOL in patients with cervical spine disease[11,19]. In our study, postoperative NDI after TDR also tended to be superior to that after ACDF. We therefore suspected that maintaining the original physiological mobility of the cervical spine not only prevented ASD but also had a positive impact on the patient's health-related QOL as well.

When performing TDR, proper surgical techniques and indications are important since reports of implant failure after TDR have been reported[22-24]. The Prestige LP cervical disc is known to be a dynamic device made of titanium-ceramic composites, comprising two thin plates that interface through a ball-in-trough mechanism to allow physiological segmental motions of the spine[25]. The two serrated keels of each endplate are then attached to the vertebral body through impaction, thereby stabilizing the implant and inducing osteointegration through a titanium plasma spray coating on the surface. This surgical technique demands not only proper decompression, but also the preservation and parallelization of the endplate, which needs to be more precise and delicate than ACDF. In fact, in this study, the operative time of TDR was approximately 40 min longer than that of ACDF. Regarding surgical indications for TDR, an interesting report in the United States exists, showing that only 43% cases met the strict indications for TDR[26]. However, in Japan, a unique and rigorous system was developed to ensure proper surgical techniques and indications of TDR. The guidelines for the appropriate use of TDR have been formulated, with regulations being established for facilities, surgeons, and surgical indications. Additionally, surgeons should undergo training in lectures and workshops, in addition to observing surgical procedures, as all surgical cases are registered in a common database. This Japanese system of TDR practice is therefore expected to reduce implant failure and further improve postoperative outcomes.

Studies have shown that TDR has specific postoperative changes, such as HO and ABL. In our study, HO and ABL were identified in 44.0% and 56.0% of patients, respectively. However, their impact on clinical outcomes is limited. Zhou *et al*. have reported in a meta-analysis that HO occurred in 8%-88% and was not associated with clinical outcomes[27]. Likewise, in a retrospective study, Kieser *et al*. reported that ABL occurred in 48%-92% of patients and did not affect the patients' clinical outcomes[17,28]. In fact, HO and ABL did not affect the surgical outcome in our study. Nevertheless, studies have reported that these severe changes were associated with clinical outcomes, such as neck pain and ROM[27,29,30]. In our data, postoperatively, there appeared to be decreased the average local ROMs at the operative level and increased the average C2-7 ROMs in the mild and severe HO subgroup; however, no statistically significant differences were found in these data between before and after surgery. We consider that further investigation with larger samples is deemed necessary.

This study has the following limitations: (1) the choice of surgical procedure, which was either TDR or ACDF, was nonrandomized; (2) the number of patients included was relatively small, and (3) the surgical evaluation was conducted on the basis of only a 1-year follow-up. Therefore, mid- and long-term results are unknown. Nonetheless, this study is the first to directly compare surgical outcomes of TDR and ACDF in Japan. A trained surgeon conducted TDR in accordance with guidelines; the short-term result would be comparable to ACDF, which is expected to prevent future ASD. Continued observation and further studies are desirable.

Conclusion

No differences in the C-JOA score and neck pain between TDR and ACDF were observed. However, a trend of better NDI score in TDR was reported. Results also showed that while the TDR maintained postoperative ROMs, the ACDF showed an increase in local ROMs at adjacent levels.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

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Y.A. and A.O. supervised the experiments; and K.S. and T.Y. wrote the manuscript.

Ethical Approval: This research has been approved by the institutional review boards of Tokyo Medical and Dental University (approval No. M2019-049) and Saiseikai Kawaguchi General Hospital (approval No. 21-18).

Informed Consent: Informed consent for publication was obtained from all participants in this study.

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