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RESEARCH ARTICLE

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Average 10-Year Follow-Up Outcomes of Lumbar Total Disc Replacement in 109 Patients

Kang-Jun Yoon

St peter's Hospital, Nambuschwanlo Gangnamgu Seoul, South Korea

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Introduction

The low back pain is common symptom in aging process. Although the causes of low back pain are various, Degenerative Disc Disease (DDD) is one of the most important disorders. The primary treatment for DDD is conservative treatment. However, if the pain persists over 6 months despite of conservative management, surgical intervention should be considered.

Over the past few decades, lumbar interbody fusion has been established as gold standard for the treatment of DDD in patients who are unresponsive to conservative treatment. However, lumbar interbody fusion for DDD is associated with various side effects including Adjacent Segment Degeneration (ASD), pseudoarthrosis, procedure related complications, and unexpected dissociation between fusion rate and clinical outcome. Therefore, Lumbar Total Disc Replacement (TDR) has been introduced alternative to fusion for treatment of DDD [1].

Theoretically, TDR preserve segmental motion and restore disc height at the treated level while removing the cause of pain in disc, which reduces ASD compared with lumbar fusion. Despite of numerous studies reporting the successful clinical outcomes, the use of TDR has been decreasing because of few evidence regarding long-term clinical efficacy such as implant survival and late complications [2-12].

The aim of this study is to report long-term serial clinical and radiological outcomes of 109 patients who underwent TDR with an average follow-up of 10 years.

Materials and Methods

Patients

A retrospective review of patients who underwent lumbar TDR was performed. Between 2005 and 2015, a total of 166 patients (186 segments) underwent lumbar TDR by highly trained single spine surgeon.

Indications for lumbar TDR were patients with chronic low back pain resistant to conservative management for at least 6 months and symptomatic lumbar DDD confirmed by Magnetic Resonance Imaging (MRI), Computed Tomography (CT), and simple radiography. Exclusion criteria for TDR were lumbar instability, scoliosis greater than 15° Cobb angle, significant facet joint arthritic change and spinal infection.

All patients were followed up at an outpatient department and were evaluated same assessment protocol at every visit. All patients provided informed consent. Among them, the patients who were followed up for more than 6 years were included in the study. 57 of the 166 patients were excluded from the study due to the early dropout before postoperative 6 year(n=39) and incomplete clinical and radiological data acquisition(n=18). Finally, 109 patients enrolled in this study with follow-up rate of 65.7%. During follow-up, 14 patients underwent revision surgery at the index segment or adjacent segment or additional surgery at lumbar other segment.

Clinical Evaluation

Experienced research assistants who were not involved in the patient management interviewed the 109 patients and evaluated clinical outcomes using visual analog scale (VAS) for low back pain, Oswestry Disability Index (ODI) at outpatient's visit. The data (preoperative, postoperative, 5 years, and the last follow up) were selected for the clinical evaluation. Clinical success was assessed using FDA definition at final follow-up [12,13]. Clinical success was defined as

- ≥ 15 point improvement in ODI,
- No device failure,
- No major complication and
- No neurological change

Additional questions were asked : " Finally, would you recommend TDR to your family or friends?" Answers were made using a 4-point scale (highly recommend, recommend, not recommend, highly not recommend).

Contact Kang-Jun Yoon, St peter's Hospital, Nambuschwanlo Gangnamgu Seoul, South Korea. Tel No: +821095774121.

Radiological Evaluation

Retrospectively, a trained spine surgeon analyzed all the plain radiographic data(preoperative, postoperative, 5 years, and the last follow up) for the radiologic evaluation. The segmental Range of Motion (ROM) of index level, Lumbar Lordosis (LL), Intervertebral Disc Height (IDH), Heterotopic Ossification (HO) were measured. The segmental ROM of index level was obtained by measuring the Cobb angle of the intervertebral space on lumbar flexion and extension images of the standing radiograph [14,15]. We defined ROM ≤3° as fused and ≥10° as unstable. The LL on the standing radiograph was measured as the angle between the upper end plate of the L1 vertebral and the upper end plate of sacrum [12]. The IDH on the simple radiograph of median sagittal position was calculated as the average value of anterior and posterior disc edge heights [15,16]. HO was assessed in accordance with the classification of McAfee [17].

Surgical Technique

All TDRs were performed through anterior retroperitoneal approach. In supine position, the body posture was kept as neutral position to maintain lordotic lumbar curvature. In L5/S1, right side approach is preferred, because the superior hypogastic plexus which may bring retrograde ejaculation in male can be easily dissected from right to left and left side is preserved for possibility of upper levels surgery in future. Above L5/S1 level, common iliac veins and Inferior Vena Cava (IVC) are usually located at right side, so left side approach is preferred. After exposure and removal of intervertebral disc at index level, surgeon must place implant in appropriate position.

Statistical Analysis

Statistical analysis was performed by an independent statistician using SPSS. Continuous variables were reported at mean ± standard deviation. Categorical variables were expressed as the number of cases or percentage. The repeated measure analysis of variance (ANOVA) was used to compare means of continuous normally distributed variables in three or more timing of measurement. P value of < 0.05 was considered statistically significant.

Results

The patient demographic and surgical data are summarized in Table 1. Total study population consisted of 109 patients with 123 segments: 109 patients included 58 males and 51 females with mean age at surgery of 56.4 ± 11.9(22-81) years. The mean follow-up duration was 122.0 ± 25.6(74-189) months. The monosegmental TDRs were performed for 95 patients at the levels L3/4(n=5), L4/5(n=51), L5/S1(n=39), and 14 patients were operated bisegmentally at the levels L3/4/5(n=5), L4/5/S1(n=9). The instruments of artificial disc used in TDR are Charite (54 levels of 43.9%), Mobidisc L (7 levels of 5.7%), ActivL (13 levels of 10.6%), INMOTION (18 levels of 14.6%), AMAV (19 levels of 15.5%), and ProDisc-L (12 levels of 9.8%).

Table 1: Patient Demographic Data

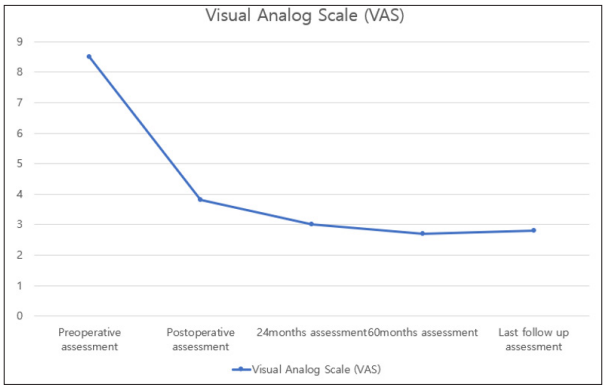
Patients	109 patients
Sex(M:F)	58 : 51
Age	56.4 ± 11.9
TDR level	Total 123 L3/4 : 10 (8.0%) L4/5 : 70 (57.0%) L5/S1 : 43(35.0%)
Mono : Bisegment	95 : 14
Manufacture	Charite : 54 (43.9%) Mobidisc L : 7 (5.7%) ActivL : 13 (10.6%) INMOTION : 18 (14.6%) AMAV : 19 (15.5%) ProDisc-L :12 (9.8%)
Mean follow up	122 ± 25.6 (74-189) months

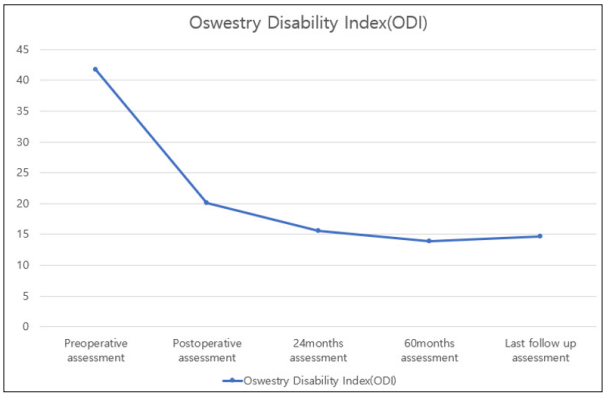
Clinical Results

Analysis of the clinical parameters have been showed significant improvement in both VAS and ODI score (p=0.000,p=0.000, respectively, repeated-measures ANOVA) (Table 2).

Table 2: Clinical Outcomes(Repeated-Measures Anova)

	PREOP	POSTOP	24months	60months	Last f/u	p
VAS	8.5 ± 1.1	3.8 ± 2.2	3.0 ± 2.2	2.7 ± 2.1	2.8 ±2.2	0.000
ODI	41.7 ± 5.0	20.1 ± 11.0	15.5 ± 11.0	13.9 ± 10.6	14.6 ± 11.5	0.000





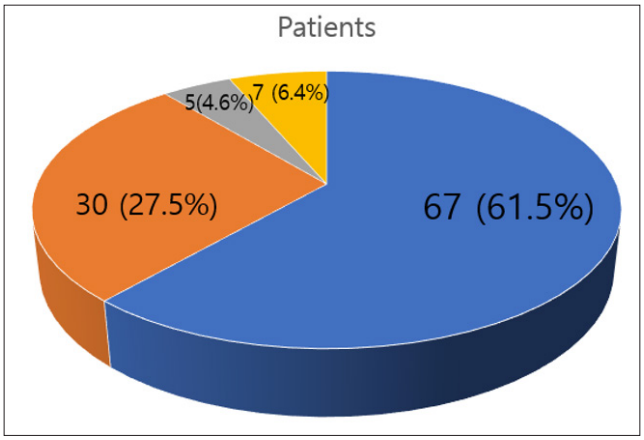
Mean preoperative VAS score (8.5 ± 1.1) was significantly decreased to 3.8 ± 2.2 (p=0.000, Bonferroni's post-hoc test) at postoperative assessment, and mean VAS score continued to decrease significantly until 5 years follow-up (2.7 ± 2.1, p=0.035, Bonferroni's post-hoc test). After then, VAS score was stable, and no statistically significant change has been identified between 5years follow-up and last follow-up (p=0.1000, Bonferroni's post-hoc test).

Postoperative changes in mean ODI score showed a similar pattern with VAS score. Mean VAS score (41.7 ± 5.0 at postoperatively) was decreased significantly at postoperative assessment (20.1 ± 11.0, p=0.000, Bonferroni's post-hoc test), 2 years follow-up (15.15 ± 11.0, p=0.000, Bonferroni's post-hoc test), and 5-year follow-up (13.9 ± 10.6, p=0.034, Bonferroni's post-hoc test). After then, ODI score was stable, and no statistically significant change has been identified between 5years follow-up and last follow up (p=1.000, Bonferroni's post-hoc test).

In terms of recommendation question, 67 patients (61.5%) answered "highly recommend", 30 patients (27.5%) "recommend", 5 patients (4.6%) "not recommend", 7 patients (6.4%) "highly not recommend". The overall satisfaction rate ("highly recommend" + "recommend") was 89.0%. (Table 3).

Table 3: Recommendation(Total Recommend : 89%)

Recommendation	Patients
Highly recommend	67 (61.5%)
Recommend	30 (27.5%)
Not recommend	5 (4.6%)
Highly not recommend	7 (6.4%)

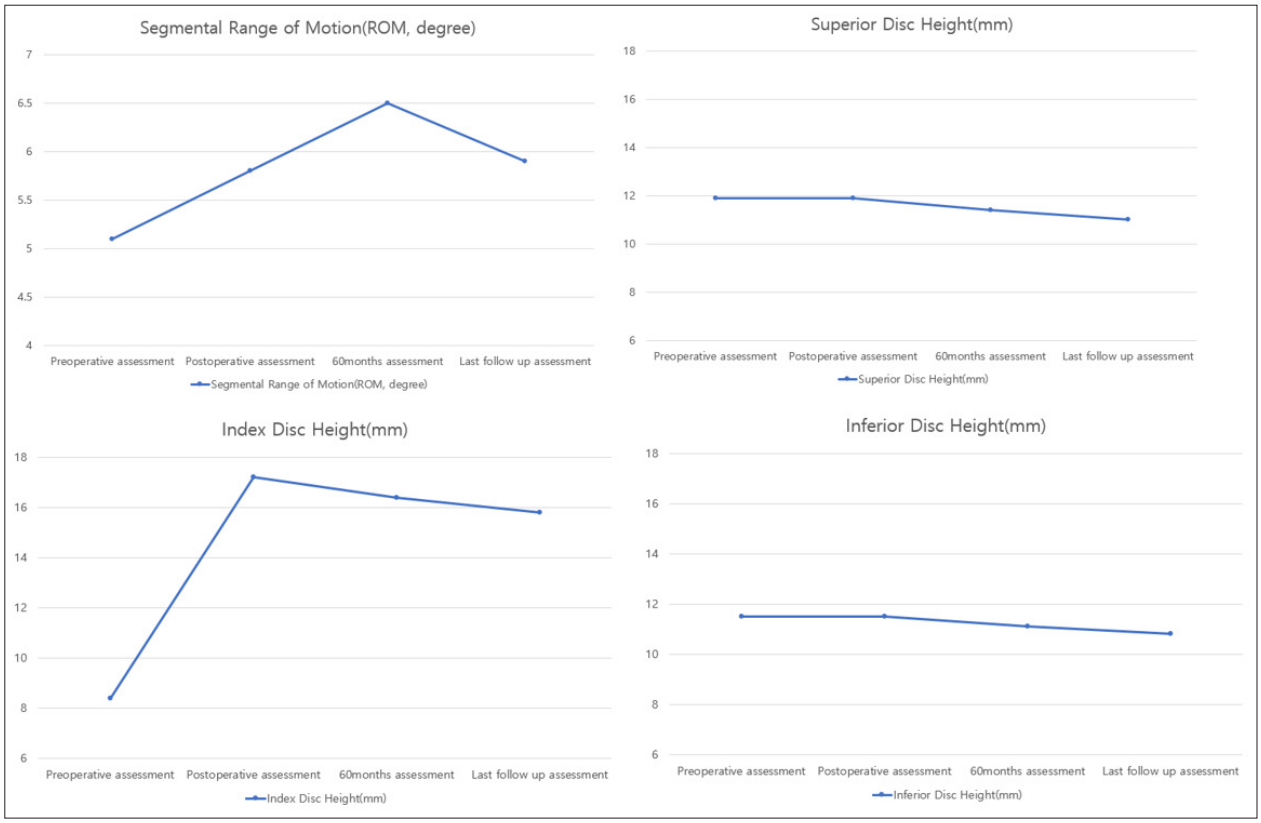


Radiologic Outcomes

Radiologic outcomes are shown in Table 4. The segmental ROM (5.1 ± 2.6 at preoperatively) was significantly increased at postoperatively (5.8 ± 2.2, p=0.041, Bonferroni's post-hoc test) and increased up to 5 years follow-up (6.5 ± 2.7, p=0.000, Bonferroni's post-hoc test). Thereafter, the segmental ROM was decreased significantly at final follow-up (5.9 ± 3.0, p=0.032, Bonferroni's post-hoc test), but it was comparable to the preoperative segmental ROM. Finally, 15(12.2%) prosthesis had an ROM no greater than 3° and 8 (6.5%) prosthesis had an ROM above 10°.

Table 4: Radiologic Outcomes(Repeated-Measures Anova)

	Preop	Postop	5yr f/u	Last f/u	P value
Segmental ROM (degree)	5.1 ± 2.6	5.8 ± 2.2	6.5 ± 2.7	5.9 ± 3.0	0.000
L1-S1 Lordosis (degree)	34.5 ± 12.6	35.9 ± 10.5	35.2 ± 12.4	37.0 ± 12.1	0.061
Sup. disc height (mm)	11.9 ± 2.1	11.9 ± 2.1	11.4 ± 2.3	11.0 ±2.2	0.000
Index disc height (mm)	9.4 ± 3.0	17.2 ± 1.8	16.4 ± 2.0	15.8 ± 2.1	0.000
Inf. Disc height (mm)	11.5 ± 2.6	11.5 ± 2.6	11.1 ± 2.7	10.8 ± 2.7	0.002
Heterotopic ossification (Friedman test)	Gr0 : 123 Gr1 : 0 Gr2 : 0 Gr3 : 0	Gr0 : 123 Gr1 : 0 Gr2 : 0 Gr3 : 0	Gr0 : 42 Gr1 : 72 Gr2 : 8 Gr3 : 1	Gr0 : 19 Gr1 : 69 Gr2 : 25 Gr3 : 10	0.000



Although LL was increased and maintained during all postoperative follow-up times compared with the preoperative LL, the statistical difference was not significant (p=0.061, repeated-measures ANOVA).

The mean IDH of index level showed a significant increase from 9.4 ± 3.0 mm preoperatively to 17.2 ± 1.8 mm postoperatively (p=0.000, Bonferroni's post-hoc test). Thereafter, although gradual decrement was observed to the last follow-up (15.8 ± 2.1, p=0.000, Bonferroni's post-hoc test), it was significantly higher than preoperative mean IDH(p=0.000, Bonferroni's post-hoc test).

There was no significant difference in mean IDH at adjacent superior and inferior levels in preoperative and postoperative measurements. However, the mean IDH of the adjacent superior segment decreased significantly to 11.0 ± 2.2 mm at final follow-up from a preoperative 11.9 ± 2.1 mm (p=0.000, Bonferroni's post-hoc test). The mean IDH of adjacent inferior segment also decreased significantly to 10.8 ± 2.7 mm at final follow-up from a preoperative 11.5 ± 2.6 mm (p=0.000, Bonferroni's post-hoc test).

HO was detected in 104 segments (84.5%) at final follow-up. According to McAfee's classification17), class 0 HO was detected in 19 segments (15.5%), class I in 69 segments (56.1%), class II in 25 segments (20.3%), class III in 10 segments (8.1%), and class IV in 0 segments. According to the class of HO, the patients divided into low grade group (Class 0 and I of HO) and high grade group (class II, III,IV of HO). The mean segmental ROM, the VAS score, and the ODI score were 6.5 ± 3.1°, 2.8 ± 2.0 point, 14.4 ± 11.1 point, respectively, in the low-grade group. The mean segmental ROM, the VAS score, and the ODI score were 4.4 ± 2.3°, 2.9 ± 2.6 point, 14.8 ± 12.9 point, respectively, in the high-grade group. The segmental ROM was significantly lower in the high-grade group than that in the low-grade group(p=0.000). However, VAS and ODI scores show no statistical significance between the two groups (p=0.752, p=0.870, respectively). Correlation between HO and clinical factor is summarized in Table 5.

Table 5: Correlation between Heterotopic Ossification and Clinical Factor

	Segment(%)	Segmental ROM(degree)	VAS	ODI
Low grade group	88(72%)	6.5 ± 3.1	2.8 ± 2.0	14.4 ±11.1
High grade group	35(28%)	4.4 ± 2.3	2.9 ± 2.6	14.8 ±12.9
p-value		P=0.000	P=0.752	P=0.870

Reoperation

Data of reoperation is demonstrated in Table 6. Revision surgeries were performed for 14 patients (12.8%) at 6.3 ± 1.1 years after the index surgery. Overall complications requiring a reoperation are provided in Table 6. The reasons for reoperation were index segment spinal stenosis in two patients, implant dislocation in two patients, implant subsidence in one patient, and adjacent segment disease in nine patients.

Table 6:Reoperation Data

No	Index level	Manufacture	Age	Sex	Time interval(months)	Cause	Operation
1	L4/5	Charite	65	F	48	ASD	ULBD, L5/S1
2	L4/5	Charite	58	F	6	Instrument failure	Fusion,
L4/5							
3	L5/S1	Charite	63	F	117	ASD	PELD,
L4/5							
4	L5/S1	Charite	46	M	130	ASD	ULBD, L4/5
5	L4/5	Charite	36	M	156	ASD	Diskectomy,
L3/4							
6	L5/S1	Charite	52	M	92	HIVD	PELD,
L2/3							
7	L4/5	Charite	70	M	3	Instrument failure	Fusion,
L4/5							
8	L3/4	Charite	70	M	45	Stenosis	ULBD, L3/4
9	L4/5	Charite	63	F	92	ASD	ULBD, L3/4
10	L5/S1	Charite	73	M	31	Stenosis	ULBD,L3/4
11	L4/5	INMOTION	49	M	36	L3 bursting fracture	Screw fixation,
T12-L4							
12	L4/5	AMAV	67	F	77	ASD	Fusion, L5/S1
13	L5/S1	AMAV	55	M	86	ASD	ULBD, L4/5
14	L5/S1	ProDisc-L	58	F	72	ASD	ULBD,L4/5

Clinical Success

The clinical success rate according to the FDA criteria at the final follow-up was 91 patients(83.5 %).(Table 7)

Table 7: Fda Clinical Success : 91/109 * 100 = 83.5%

FDA clinical sucess	Neither 15 or more point improvement in ODI	device failure	Major complications	Neurological change
	16	3	0	2

All of these cases improved ODI by more than 15 points compared to preoperative ODI and had no device failure, major complications, and neurological deficit. The only failure of ODI improvement by more than 15 points were 14 patients. The only device failure was 1 patient. The only occurrence of neurological change was 1 patient. The 1 patient had failure of ODI improvement and device failure. The 1 patient had of ODI improvement, device failure and neurological change.

Discussion

Several publications on outcomes after lumbar TDR have been reported [1,12,18-24]. However, to date, the number of studies that have addressed long-term outcome of more than 100 patients after TDR is limited. Therefore, the purpose of this study was to evaluate long-term clinical and radiological outcomes of 109 patients who underwent TDR with an average follow-up of 10 years.

This study demonstrates satisfactory results in regard to clinical as well as radiological outcomes. From the overall standpoint, our results show a significant improvement of VAS and ODI scores after a mean 10-year follow-up and produce the clinical success rate of 83.5% and the subjective satisfaction rate(recommendation) of 89%.

The total VAS and ODI scores decreased significantly postoperatively, reaching the maximal improvement at the postoperative 5years. Thereafter, although the total VAS and ODI scores slightly increased at last follow-up, they showed no statistical significance and the significant improvement from baseline was maintained. The patterns of clinical score are comparable to the previous long-term studies.1,12,19,25,26) According to Park et al12), the VAS and ODI scores continued to decrease until postoperative 2 years. Afterward, the scores increased but maintained significantly lower than baseline. Although there are differences in the timing of

the rebound depending on study, the postoperative improved clinical scores remained lower than baseline even after average 10 years of long-term follow-up.

The satisfaction rate is one of the essential measurements of clinical outcomes because it represents a patient's subjective result. To assess the satisfaction rate, we asked the patients that "Finally, would you recommend TDR to your family or friends?". 97 (89%) of 109 patients answered "recommend" or "highly recommend". According to Tropiano's study of 55 patients with 7-to-11-year follow-up after lumbar TDR with a ProDisc-L, the satisfaction rate was 90.9% [25]. Siepe et al reported the clinical results of 181patients with a mean follow-up of 7.4 years and the satisfaction rate was 86.3% [19]. These are similar with our result of 89% satisfaction rate. However, Putizer et al reported the satisfaction rate was 75% at mean 17-year follow-up using Charite' prosthesis [9]. As in the result of several studies, the VAS and ODI increase up slightly after postoperative 5 years, it is natural that longer follow-up study results in lower clinical outcomes.

The major purpose of TDR is to preserve the segmental motion. It is intended to provide dynamic stability and prevent junctional degeneration at the adjacent segments. Therefore, the success of the TDR surgery depends on the achievement of physiological segmental ROM. According to Lu's study of average 15.2 years follow-up, segmental ROM at final follow-up showed decreasing trend from the the preoperative ROM but with no significant difference [15]. However, they were not evaluated segmental ROM at immediate postoperatively, 2 years and 5years follow-up. Park el al reported that the segmental ROM was significantly increased up to 2 years follow-up in monosegmental TDR($p<0.001$,$p=0.0040$, respectively) [12]. Thereafter, the segmental ROM decreased until the last follow-up, but the last ROM was comparable to the preoperative ROM. This result is compatible with our study. In our study, the segmental ROM was significantly increased up to 5years follow-up and showed decreased trend afterward, but it was comparable to preoperative ROM. The reported mean ROM in surgical segment ranges from 3.8° to10.3° [15, 27,28]. The patients with segmental ROM<2° are 20(34.5%) in Huang et al. and 9(9%) in Lemaire et al. [27,28]. In our study, at final follow-up, the mean ROM in surgical segment is 5.9° and 15(12.2%) surgical segments had an ROM no greater than 3°. It is natural that the segmental ROM of either an intact disc or an artificial disc will decrease with age. The possible causes of decreased segmental ROM are the postoperative formation of connective tissue, loss of IDH, hyperostosis and natural aging of the entire spine and the disc [29]. Among them, HO is the major cause of decreased ROM.

The etiology of HO is unclear. The incidence of the HO is about 15% in short-term follow-up studies and 50-74.3% in long-term follow-up studies [9,15,30-33]. Numerous studies reported that HO limits the ROM of the ossified segment but is not correlated with clinical outcomes [12,33,34]. In consistent with these studies, our study detected 104 segments (84.5%) of HO at final follow-up. The segmental ROM at final follow-up was significantly lower in the high grade group (class II,III,IV) than in the low grade group(class 0,I)($p=0.000$). However, VAS and ODI scores show no statistical significance between the two groups.

Godde et al reported that fusion can significantly reduce LL. In addition, this reduction of the LL is correlated to postoperative back pain [35-37]. However, whether lumbar TDR influence LL and whether the LL is correlated to clinical outcomes are still controversial.38) Tournier et al. evaluated 105 patients and noted a significant increase in LL in patients with TDR(L1-S1 angulation improved from 50 to 52 degree) [38]. In our study, the LL changed with TDR surgery but the change do not have statistical significance when compared with preoperative LL($p=0.061$). However, LL was well maintained during all follow-up evaluation.

Another major purpose of TDR is to restore disc height to an optimal level. Restoring disc height reduce loading of facet joint, which might delay facet joint hypertrophy and reduce low back pain originated from facet joint. In addition, restoring disc height increase intervertebral foraminal height and prevent neurologic symptoms from exiting root compression. McAfee et al reported TDR with the CHARITE artificial disc resulted in significantly better restoration of disc space height, and significantly less subsidence than anterior interbody fusion with BAK cages during the first 2 years following surgery [39]. In the present study, the immediate postoperative mean IDH at index level was increased significantly($p=0.000$), but gradual decrement was observed to final follow-up. However, the mean IDH at final follow-up was significantly higher than the mean preoperative value($p=0.000$).

ASD after fusion surgery is related to increased stress at adjacent segments due to transfer of extra motion and loads from decreased segmental mobility of the fused segment [40]. TDR was developed to avoid this negative effect of fusion surgery by preserving motion segment. Zigler et al.41) reported the patients treated with TDR showed significantly lower rate of ASD than that with circumferential fusion in 5-year follow-up. The study of mean 15.4 years follow-up of TDR by Lu et al. reported the mean IDH of the adjacent superior segment decreased to 9.8mm at final follow-up from a preoperative 10.1mm [15]. The adjacent inferior segment showed an increasing trend (6.6mm preoperatively to 7.4 mm at final follow-up), but no statistically difference was found in either group. In the present study, to assess ASD, the IDH of superior and inferior segment was evaluated. The mean IDH of the superior and inferior adjacent segment decreased significantly to final follow-up. However, the mean change was less than 1mm for average 122 months follow-up and it can be consider as natural degenerative change.

There is still debate concerning the use of TDR in terms of fear of deteriorating effect and high rates of late revision surgery [19, 42]. To assess this issue, the accumulation and analysis of long-term data are paramount. There are several studies with a long term follow-up. They reported a reoperation rate ranging from 5 to 33% [9-12,18,43-45]. Three studies by Meir et al. Laugesen et al. and Kitzen et al. reported a revision rate of more than 30% with possible cause related to TDR prosthesis design and patient selection criteria [43-46]. According to Maruenda et al., the reoperation rate to address ASD after lumbar fusion was 24.6% at 10 years follow up. Ghiselli et al reported the reoperation rate to address ASD after lumbar fusion was 16.5% at 5 years and 36.1% at 10 years follow up [47,48]. In our study, overall reoperation rate of 12.8% was similar to that of 13% in the study of David et al [11]. In addition, the reoperation due to ASD after TDR was 8.3%. Therefore, in terms of reoperation rate at 10 years follow-up, the result of this study is superior to

that of lumbar fusion.

In this study, the clinical success rate according to FDA criteria at last follow-up was 83.5%. It is higher than the clinical success rate of 66.7% in mean 10-year follow-up study using ProDisc-II of Park et al. and that of 71.4% in mean 6 years follow-up study using ProDisc-L of Park et al. [12,1]. According to Guyer et al., the clinical success rate of anterior lumbar interbody fusion at postoperative 5years follow-up was 51.2%. These results demonstrate that TDR have advantage in terms of long-term outcome and safety of instrumentation compared with lumbar fusion [49].

Despite of meaningful results, our study has several limitations. First, this study is limited by its retrospective nature. Second, for large cohort and long-term follow-up, we could not unify manufacturer of instrument used in TDR surgery. Third, radiological factor was measured based on the plain radiographic study and lacked evaluation of endplate sclerosis and spondylolisthesis for ASD. Therefore, further evaluation using computed tomography and magnetic resonance imaging is needed to assess ASD and facet joint hypertrophy more exactly.

Conclusion

This study demonstrates successful clinical and radiological results in long term follow-up. Therefore, Lumbar TDR can be a safe and effective alternative to treat lumbar DDD. TDR not only maintain ROM but also restore IDH of index segment, being a safe and effective alternative to treat lumbar DDD. However, since the most of clinical effect decreases after postoperative 5 years follow-up, careful approach is necessary considering the patient's age and degree of disc degeneration.

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