

Review Article

Two- and five-year follow-up of lumbar total disc replacement compared to fusion: a meta-analysis

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Abstract: Lumbar fusion surgery has been a gold standard for treating lumbar disc degenerative disease (LDDD). But the adjacent segment pathology (ASP) became a problem, which could have been caused by the increased motion and stress concentration at the adjacent segment. So, artificial total disc replacement (TDR) as an alternative to spinal fusion has recently been applied for treatment of LDDD. However, up to now, a controversy whether TDR is better than fusion still persists. We performed the research of database including Pubmed/Medline, EMBASE, and Ovid. Our studies were classified into short-term (2 years) and midterm (5 years) follow-up. Twelve randomized controlled trials involving 1479 cases were included in the study. The repetitive data from them were excluded. Significant difference in visual analogue scale (VAS) and Oswestry disability index (ODI) could be found at 2 year follow-up, and TDR group was better than fusion group in both of them (VAS: $I^2=0\%$, $P<0.0006$; ODI: $I^2=0\%$, $P<0.00001$). No difference was found in reoperation rate at 2 year follow-up ($I^2=18\%$, $P=0.22$). However, the reoperation rate at the index level in TDR group was significantly lower than that in fusion group at 5 year follow-up ($I^2=0\%$, $P=0.006$). The incidence of ASP in TDR group was lower compared with fusion group at 5 year follow-up ($I^2=0\%$, $P<0.0002$) but not at 2 year follow-up ($I^2=0\%$, $P<0.08$). TDR shows the efficacy and safety comparable to lumbar fusion at 2 and 5 year follow-up. Besides, TDR has significant superiority in a lower incidence of ASP at 5 year follow-up.

Keywords: Lumbar total disc replacement, lumbar fusion, meta-analysis

Introduction

The rapid increase of the elderly population has resulted in increased prevalence of lumbar degenerative disc disease (LDDD). The symptom of LDDD varies in low back pain and radiating pain of lower extremity, which impacts people's quality of life and increases economic burden of society. Fusion surgery has been a gold standard for treatment of symptomatic LDDD by regaining the stability of spine and may reduce the incidence of low back pain [1, 2]. However, with the increasing number of fusion surgery a lot of problems have appeared lately. New instability and pain came out that may be due to the concentrated stress on the adjacent segments [3, 4]. So, artificial total disc replacement as an alternative to spinal fusion has been applied for treatment of LDDD, which can theoretically reduce the incidence of adjacent segment pathology (ASP) by restoring and maintaining the segment kinematics after disc

replacement. There has been a controversy whether TDR is more effective and safer than lumbar fusion for a long time. Many randomized controlled studies have been carried out to compare TDR with lumbar fusion techniques. And meta-analysis has been performed for finding the truth. But all of the meta-analysis were based on the short-term follow-up results at 2 years [5]. Sequential comparison is necessary for confirming which type of surgery is better.

The aim of this meta-analysis study is to systematically compare the efficacy and safety of TDR with those of fusion surgery in the treatment of LDDD at 2 and 5 year follow-up.

Material and methods

Search methods and selection criteria

Up to April 2015, all published randomized controlled trials (RCTs) comparing TDR with lumbar fusion surgery for the treatment of LDDD were

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Table 1. Modified Jadad scale with eight items

Items assessed	Response	Score
Was the study described as randomized?	Yes	+1
	No	0
Was the method of randomization appropriate?	Yes	+1
	No	-1
	Not described	0
Was the study described as blinded?	Yes	+1
	No	0
Was the method of blinding appropriate?	Yes	+1
	No	-1
	Not described	0
Was there a description of withdrawals and dropouts?	Yes	+1
	No	0
Was there a clear description of the inclusion/exclusion criteria?	Yes	+1
	No	0
Was the method used to assess adverse effects described?	Yes	+1
	No	0
Was the method of statistical analysis described?	Yes	+1
	No	0

searched by two authors independently. We performed the search of database including Pubmed/Medline, EMBASE, and Ovid. The search strategy consisted of a combination of key words such as lumbar degenerative disc disease, artificial total disc replacement, lumbar disc replacement, lumbar fusion, lumbar arthroplasty, and randomized controlled study. The search was limited to studies published in English. Studies were randomized controlled trials, and published in a peer-reviewed journal as full article, excluding grey literature and conference proceedings.

Data extraction

Three reviewers participated in data extraction from the included studies. Two reviewers (Lei Ma and Hui Wang) extracted all the data independently from the included studies, and the other reviewer (Si-Dong Yang) checked the data. The data extracted in this study included study design, age, gender and type of fusion procedure. The outcome assessment in this analysis included visual analogue scale (VAS), Oswestry disability index (ODI), intra-operative blood loss, operating time, proportion of full-time/part-time work, range of movement (ROM), infection rate, reoperation rate, and incidence of adjacent segment pathology (ASP). Where there was any uncertainty or discrepancies, the article was discussed among the three authors

to determine if the studies should be included. We also contacted authors if there were any issues that needed to be clarified.

Methodological assessment and assessment of risk of bias

The modified Jadad scale was used to assess methodological quality in this study [6]. There are twelve items designed to assess randomization, blinding, withdrawals/dropouts, including and excluding criteria, adverse effects and statistical analysis (**Table 1**). The scores range from 0 to 8. Scores of 0-3 indicate poor to low quality and 4-8 good to excellent quality.

Measures of the treatment effect and assessment of the heterogeneity

The RevMan software (RevMan Version 5.2; The Nordic Cochrane Center, The Cochrane Collaboration, Copenhagen, Denmark) was used in this study. The results were expressed in terms of mean difference (MD) and 95% confidence interval (95% CI) for continuous outcomes, or in terms of odds ratio (OR) and 95% CI for dichotomous outcomes. The Q - and I^2 were used to test for statistical heterogeneity [7, 8]. The test statistic was distributed as χ^2 , Q statistics was used to evaluate heterogeneity, with its P values revealed by the forest plot. I^2 was used to estimate the size of the heterogeneity. $I^2 > 50\%$ indicates considerable heterogeneity among the included studies, and then a random-effects analysis was performed in meta-analysis. Random-effects model was used for statistical combination of low back pain (LBP) trials. These data were calculated when one outcome was assessed in different ways in different trials. A level of $P < 0.05$ was considered statistically significant.

Subgroup analyses

As control groups in these articles included two different surgical approaches, studies were divided into anterior and posterior fusion groups, and two groups were compared with TDR separately to decrease the heterogeneity.

Results

Search results

The process and results of searching the database to retrieve the relevant literature are shown in **Figure 1**. 12 published RCTs were

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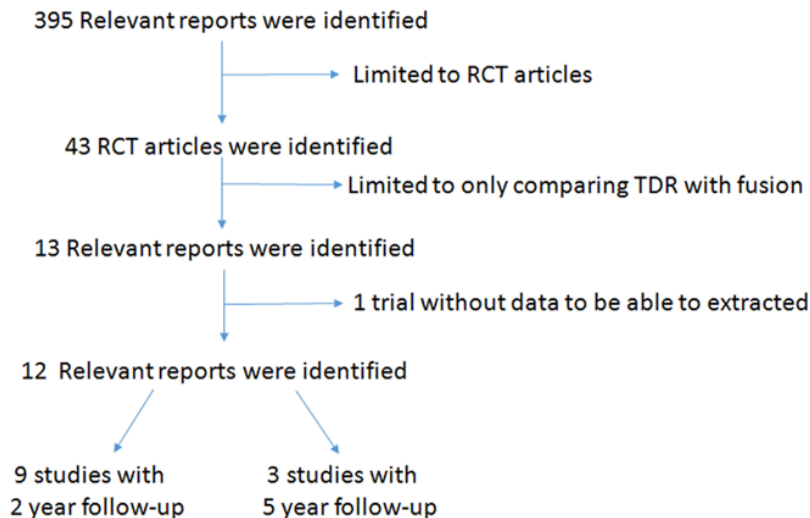


Figure 1. Flowchart showing the procedure of identification, inclusion, and exclusion of the randomized controlled trials (RCTs).

included according to the inclusion criteria [9-20]. The characteristics of the studies and participants are presented in **Table 2**. As shown in the **Table 2**, it is clear that most of the studies had high quality according to the Jadad scale. But all the studies were not using blinding method, which might lead to bias in the result. There were nine studies with 2 years' follow-up and three with 5 years' follow-up. Some of the studies shared the same demographic data of patients while focusing on different items of study. Some studies at 5 year follow-up were the extended term of follow-up of existing studies. For example, Berg 2009 [15], Berg 2011 [17], and Sköld 2013 [20] shared the same demographic data of patients with different terms of observation. The same phenomenon can also be found among the studies of Blumenthal 2005 [9], Holt 2007 [13], and McAfee 2005 [11], as well as among the studies of Ziglar 2007 [12], Delamarter 2011 [16], and Ziglar 2012 [19]. So we excluded the repetitive data from them.

Meta-analysis results

Surgical outcomes in both TDR and fusion groups showed statistically significant improvement, compared with baseline, respectively, at two- and five-year follow-up. The differences between two groups were shown as follows.

Surgical outcomes

Significant difference in VAS and ODI scores could be found at 2 year follow-up, and TDR

group was better than fusion group in both of them (VAS: $I^2=0\%$, $P<0.0006$; ODI: $I^2=0\%$, $P<0.00001$), while there was no difference at 5 year follow-up (VAS: $I^2=0\%$, $P=0.1$; ODI: $I^2=0\%$, $P=0.08$) (**Figures 2-5**). No difference was found in full-time/part-time work between TDR and fusion groups at 2 year follow-up ($I^2=0\%$, $P=0.47$) (**Figure 6**).

Operation-related data and complications

Compared with posterior approach fusion group, operation duration was significantly shorter and blood loss was less in TDR group (operating time: $I^2=0\%$, $P<0.00001$; blood loss: $I^2=11\%$, $P<0.00001$) (**Figures 7, 8**). Infection rate in fusion group was significantly higher than that in TDR ($I^2=0\%$, $P=0.03$) (**Figure 9**). No difference between two groups was found in reoperation rate at 2 year follow-up ($I^2=18\%$, $P=0.22$) (**Figure 10**). However, the reoperation rate at the index level in TDR group was significantly lower than that in fusion group at 5 year follow-up ($I^2=0\%$, $P=0.006$) (**Figure 11**).

ROM at the index level and incidence of ASP

ROM at index level in TDR group was significantly higher than that in fusion group both at 2 and 5 year follow-up (2 year: $I^2=91\%$, $P<0.00001$; 5 year: $I^2=0\%$, $P<0.00001$) (**Figures 12, 13**). The incidence of ASP in TDR group was lower than that in fusion group at 5 year follow-up ($I^2=0\%$, $P<0.0002$) but not at 2 year follow-up ($I^2=0\%$, $P<0.08$) (**Figures 14, 15**).

Discussion

Bias and control of heterogeneity

As the number of published studies is limited, there are only 12 articles in this meta-analysis. As shown in the **Table 2**, most of the studies are high quality according to the Jadad scale, and all of the included studies are well-designed RCT studies. For avoiding the heterogeneity, the sensitivity analysis was performed in this study. When comparing the blood loss between TDR

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Table 2. Main characteristics of studies included in the meta-analysis

	Patients	Patients	Mean age (y)	Mean age (y)	Male %	Male%	Surgical	Follow-up	Jadad
	No. TDR	No. Fusion	TDR	Fusion	TDR	Fusion	approach Fusion		
Blumenthal et al. 2005 [9]	205	99	39.6	39.6	55.1	44.4	Anterior	2	5
Dlamarter et al. 2005 [10]	56	22	39.7	44.2	57	45	Posterior	2	3
Mcfee et al. 2005 [11]	205	99	39.6	39.6	55.1	44.4	Anterior	2	5
Zigler et al. 2007 [12]	161	75	38.7	40.4	50.9	45.3	Posterior	2	4
Holt et al. 2007 [13]	205	99	39.6	39.6	55.1	44.4	Anterior	2	5
Guyer et al. 2009 [14]	90	43	40	38.8	52	56	Anterior	5	5
Berg et al. 2009 [15]	80	72	40.2	38.5	40	42	Posterior	2	5
Delamarter et al. 2011 [16]	174	82	41.8	41.8	57.6	54.2	Posterior	2	5
Berg et al. 2011 [17]	80	72	40.2	38.5	40	42	Posterior	2	5
Gornet et al. 2011 [18]	405	172	39.9	40.2	50	50.6	Anterior	2	6
Zigler et al. 2012 [19]	123	43	38.3	40.5	50.4	41.9	Posterior	5	4
Sköld et al. 2013 [20]	80	71	40.2	38.5	40	42	Posterior	5	5

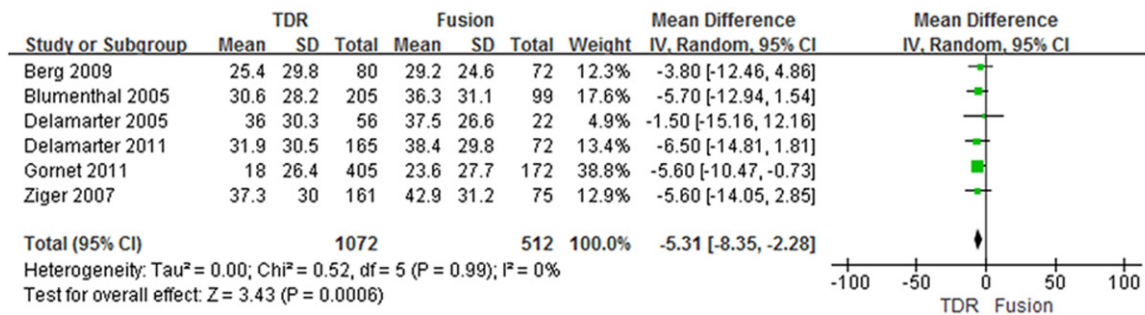


Figure 2. Meta-analysis for the visual analogue scale (VAS) for TDR and fusion groups at 2-year follow-up.

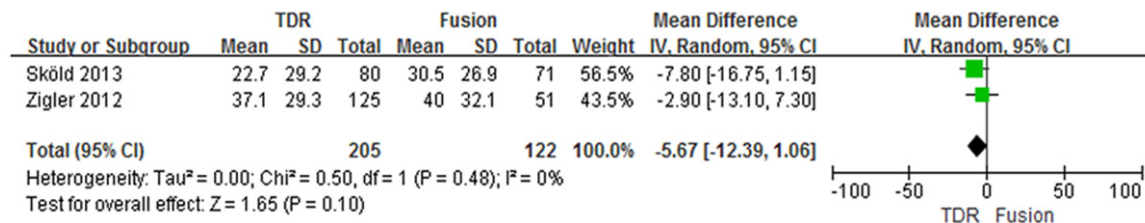


Figure 3. Meta-analysis for the visual analogue scale (VAS) for TDR and fusion groups at 5-year follow-up.

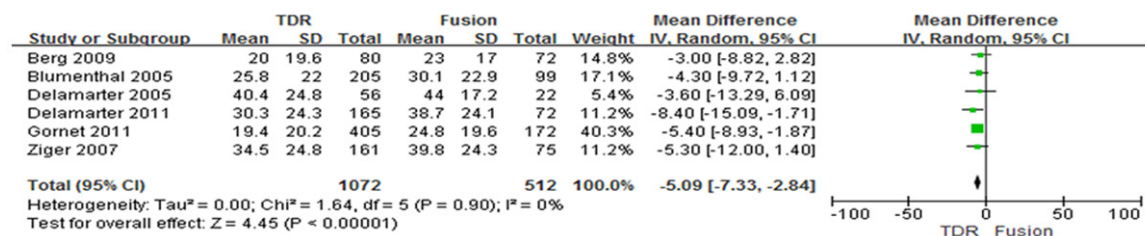


Figure 4. Meta-analysis for the Oswestry disability index (ODI) for TDR and fusion groups at 2-year follow-up.

and fusion groups, I² decreased from 93% to 11% after excluding the study of Berg 2009

[15]. When the same procedure was used to compare the operating time and reoperation

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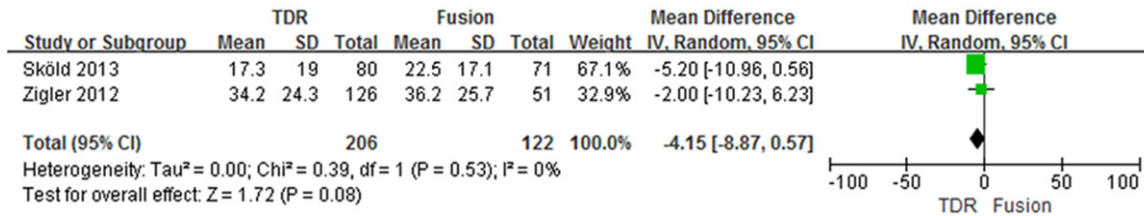


Figure 5. Meta-analysis for the Oswestry disability index (ODI) for TDR and fusion groups at 5-year follow-up.

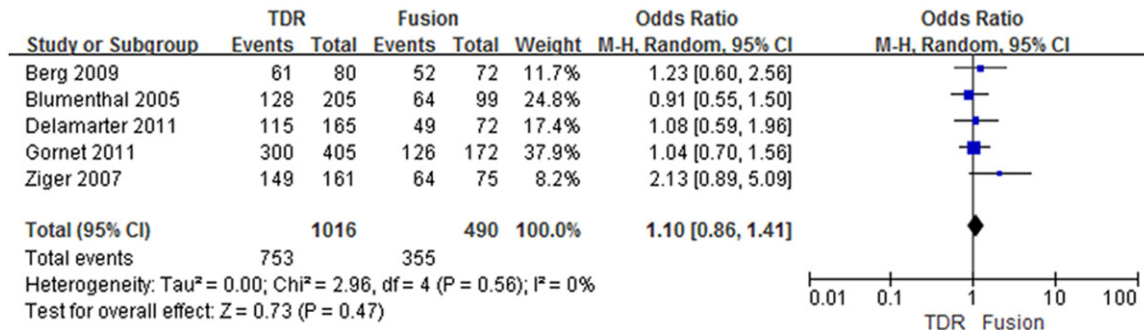


Figure 6. Meta-analysis for the proportion of full-time/part-time work for TDR and fusion groups at 2-year follow-up.

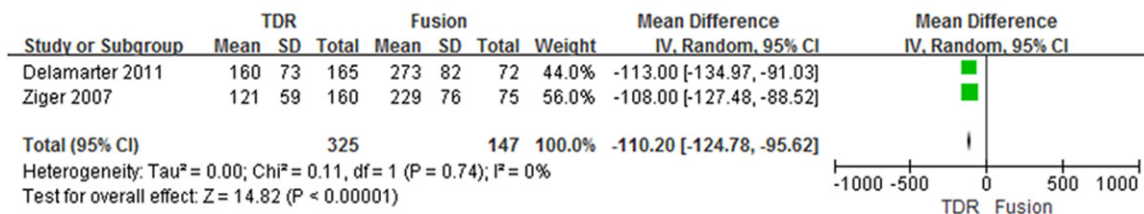


Figure 7. Meta-analysis for operation duration for TDR and fusion groups.

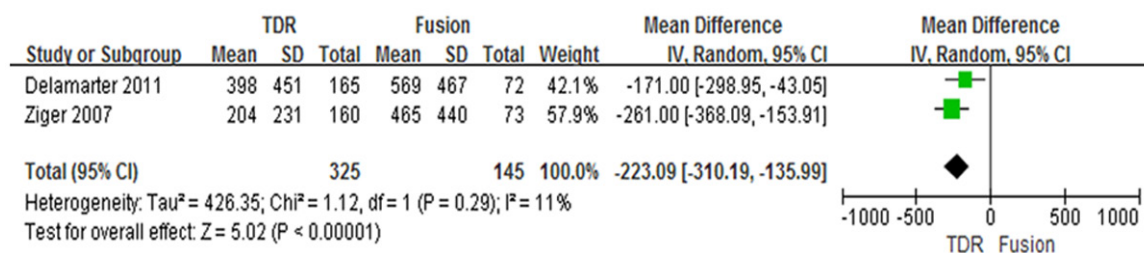


Figure 8. Meta-analysis for blood loss for TDR and fusion groups.

rate between two groups, I² changed to less than 50%. The appearance of the heterogeneity may be due to the variety of the operative experience of surgeons. I² of the ROM at 2 year follow-up was 91% while the result was accepted. Because it was well acknowledged that ROM in TDR group was higher than that in fusion group, both studies in this study show the same result.

Efficacy and safety

Lumbar fusion has been a golden standard for the treatment of LDDD [21-25]. But the fact that lumbar fusion leads to increases in ASP has become an important issue in spine surgery [26-28]. TDR, as an alternative surgery, has become more and more popular recently. However, there are still debates about which is

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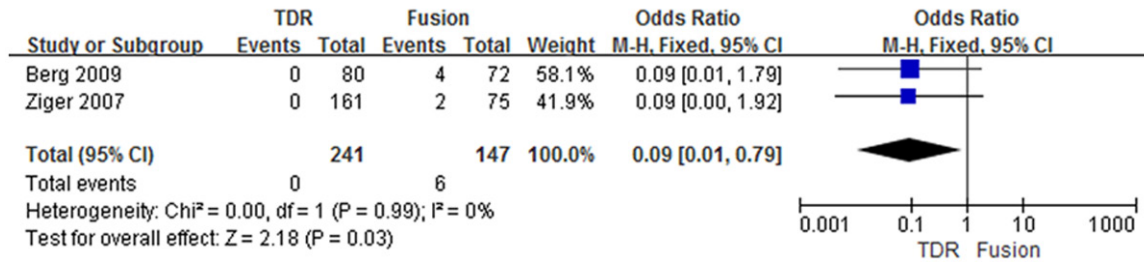


Figure 9. Meta-analysis for the incidence of infection for TDR and fusion groups at 2-year follow-up.

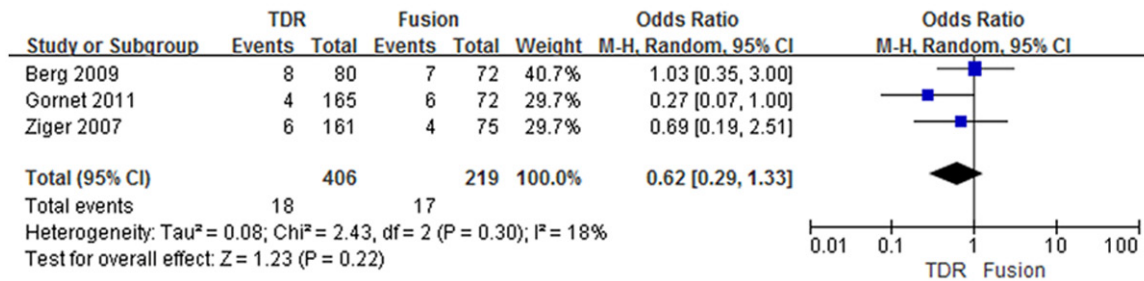


Figure 10. Meta-analysis for the reoperation rate for TDR and fusion groups at 2-year follow-up.

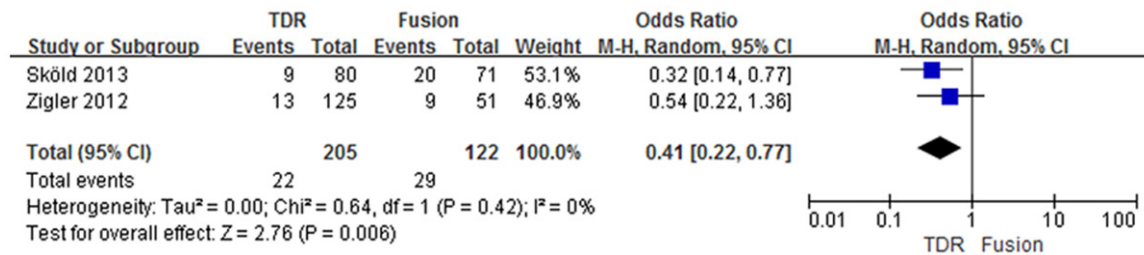


Figure 11. Meta-analysis for the reoperation rate at the index level for TDR and fusion groups at 5-year follow-up.

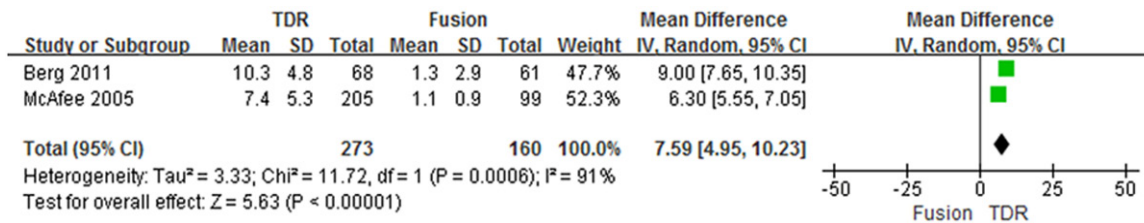


Figure 12. Meta-analysis for the index-level range of motion (ROM) for TDR and fusion groups at 2-year follow-up.

better for treating LDDD. Up to now, a lot of studies including meta-analysis show the superiority of TDR in improving physical function and decreasing lumbar pain [29], but all of them were short-term follow-up. In this meta-analysis study, the comparison of consecutive 2 year with 5 year follow-up was performed. Efficacy, safety and complications were compared between two groups at 2 and 5 year follow-up separately.

VAS and ODI scores in TDR group show a significant superiority to fusion group at 2 year follow-up, but no difference between two groups was found at 5 year follow-up. Meanwhile, the proportion of full-time/part-time work was equal in the two groups. A lot of previous studies also showed the similar changes in the VAS and ODI at 2 year follow-up [10-12]. The reason why VAS and ODI scores is reduced faster in TDR group than in fusion group has not been clear. It is

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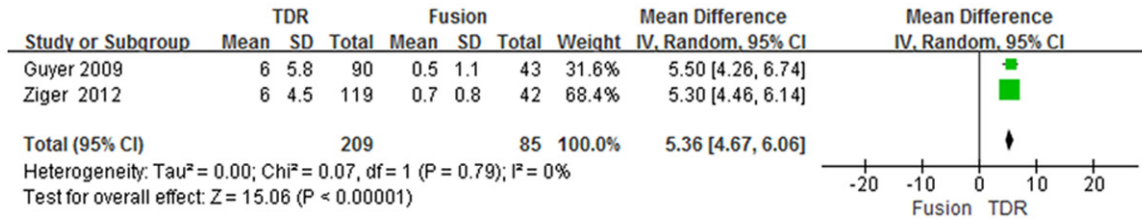


Figure 13. Meta-analysis for the index-level range of motion (ROM) for TDR and fusion groups at 5-year follow-up.

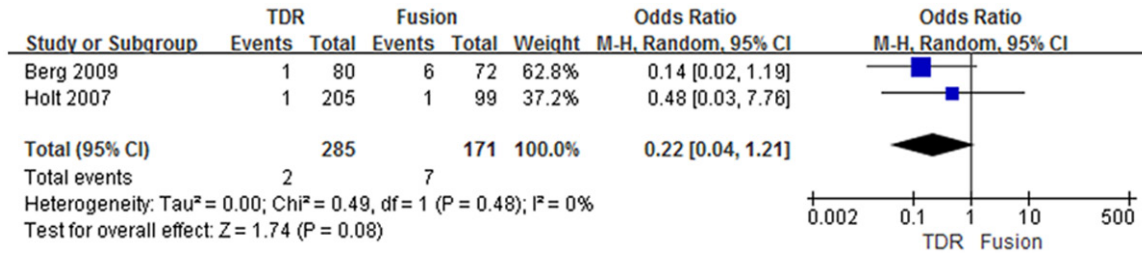


Figure 14. Meta-analysis for the incidence of adjacent segment pathology (ASP) for TDR and fusion groups at 2-year follow-up.

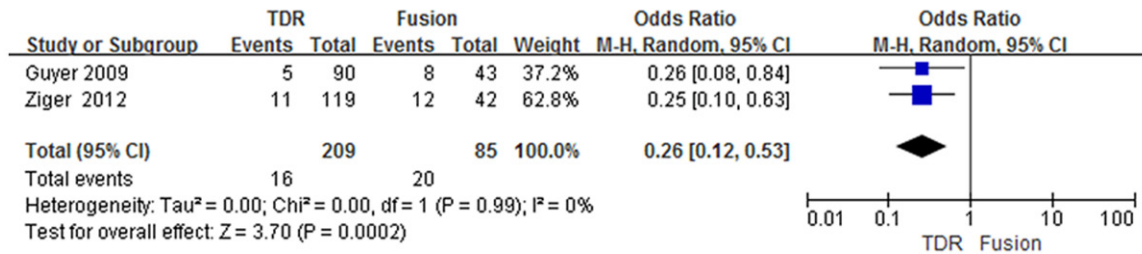


Figure 15. Meta-analysis for the incidence of adjacent segment pathology (ASP) for TDR and fusion groups at 5-year follow-up.

speculated that the effects of mechanical loading on the adjacent segment in TDR was smaller than those in fusion group. After the fusion surgery excessive load and motion at the adjacent segment, which lead to the generalized joint laxity, may cause the low back pain [30], while TDR might conserve the motion at index level and reduce it significantly. So, the efficacy of TDR was better than the fusion at 2 year follow-up and comparable to fusion at 5 year follow-up. However, more studies with longer-term follow-up are needed to confirm these findings.

In this study, compared with posterior approach fusion group, operating time was significantly shorter and blood loss was less in TDR group, which may be one cause of the higher infection rate in posterior fusion group than in TDR group. However, different results could also be

found. Zigler et al. reported that operative time for TDR was significantly shorter than that in fusion [12], while Gornet et al. reported that the operative time was longer for the TDR group and there was significant difference in operative time between two groups [18]. Blumenthal et al. reported that there was no significant difference in operative time between TDR and fusion groups [9]. The contradictory results may be partly depending on the familiarity with the surgery. Reoperation rate, as another safety item in this study, had no significant difference between two groups at 2 year follow-up, but it was significantly lower at the index level in TDR than in fusion at 5 year follow-up. Sköldet et al. reported that the reoperation rate at the index level was 8.3% for the fusion group and 6.3% for the TDR group at 5 year follow-up [20]. A recent study with 11 year follow-up shows that no reoperation was needed for implant fail-

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ures in TDR groups [31], which is much lower than the data reported previously for 0-28.6% [32-36]. But most of these studies were not RCT, and more RCT studies with long-term follow-up were needed. Based on the present data, we can draw a conclusion that TDR may be superior than fusion with shorter operative time, lower infection rate and reoperation rate. Therefore, the TDR may be safer than fusion surgery to some extent.

Incidence of ASP

Adjacent segment pathology (ASP) has been a problem following lumbar spinal fusion surgery [37, 38]. Several postoperative factors leading to ASP may include facet joint injury caused by instrument, sagittal malalignment of the spine and so on [30]. Many scholars reported that the changed biomechanics after fusion and the increased adjacent-level intra-discal pressure could play an important role in acceleration of ASP [39]. It was approved by the cadaveric study that the increased mobility of the adjacent segment may be due to the compensatory mechanism after fusion surgery [40]. Harrop et al. found that the incidence of ASP with symptoms was 14% in fusion surgery [28]. Because the TDR may retain the motion of the index level and dispense the loading stress, it could reduce incidence of ASP theoretically. Based on the results in this study, the ROM of the index level in TDR group was much higher than that in fusion group at both 2 and 5 year follow-up, which implies the conservation of motion function at index level. The incidence of ASP in TDR group was lower than in fusion group at 5 year follow-up but not at 2 year follow-up. Other studies, including 1- to 11-year follow-up, also show the positive results on the decreased incidence of ASP after TDR [34, 41]. Zigler et al. systematically compared the postoperative ASP between the TDR and fusion groups whose baseline data of lumbar disc degeneration were same before the surgery. They found the significant difference in the incidence of ASP between the two groups, with the incidence of ASP being 9.2% in TDR group and 28.6% in fusion group, respectively, after the surgery [19]. The reoperation rate for adjacent-segment disease in that study was reported for 4.0% of fusion patients and 1.9% of TDR patients without significant difference [19]. Based on their data, conclusion could be drawn that compared with fusion surgery the incidence of ASP is lower in TDR.

There were also limitations in this study. First, because of the limited number of 5 year follow-up studies, the accuracy of the results may be affected. More RCT with long-term follow-up are needed for the further study. Second, there were two studies without adequate allocation concealment, which may lead to bias. Third, the surgical proficiency varies a lot in different studies, and this may affect the surgical security-related data.

Conclusion

Surgical results in TDR are comparable with fusion surgery, and the midterm incidence of ASP in TDR is significantly lower than that in fusion surgery.

Disclosure of conflict of interest

None.

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