

Original Article

Comparison of two interspinous spacers for treatment of moderate lumbar spinal stenosis: a meta-analysis of prospective randomized controlled trials

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Abstract: Aim: Both Superion and X-Stop interspinous spacers have been approved by Food and Drug Administration (FDA) for the treatment of neurogenic claudication secondary to lumbar spinal stenosis (LSS). However, controversy remains as to the difference in the improvement of clinical outcomes in moderate LSS patients treated with the two interspinous spacers. Our purpose was to comprehensively appraise the difference. Methods: We searched multiple databases for literature retrieval. The difference in the improvement of Zurich Claudication Questionnaire (ZCQ) patient satisfaction, Visual Analog Scale (VAS) back pain, VAS leg pain and Oswestry Disability Index (ODI) was assessed between the two spacers after treatment. And the difference in the occurrence rate of adverse events between the two groups was also appraised. The Standardized Mean Difference (SMD)/risk ratio (RR) with corresponding 95% confidence interval (CI) for each parameter was estimated. Results: There was significant difference in the improvement of ZCQ patient satisfaction and VAS back pain between the two spacers (ZCQ:SMD = 0.242, $P < 0.001$; VAS back pain:SMD = 0.147, $P = 0.012$), whereas no significant difference was detected in the improvement of VAS leg pain and ODI, and the occurrence rate of adverse events between the two treatment. Conclusion: Our meta-analysis suggests that moderate LSS patients receiving X-Stop interspinous spacer have significantly higher patient satisfaction and larger reduction in the back pain severity than those implanted with Superion after surgery.

Keywords: LSS, superion, X-Stop, interspinous spacer, meta-analysis

Introduction

Lumbar spinal stenosis (LSS) is a progressive clinical entity that is defined as a narrowing of the surface area of the lumbar spinal canal and/or intervertebral foramina [1, 2]. Patients with LSS usually experience pain in the legs and low back, neurogenic claudication and radiculopathy resulting from nerve root compression [1, 3]. Nocturnal leg cramps and neurogenic bladder symptoms are also documented as clinical characteristics of LSS, which has adverse impact on the quality of life among patients [4]. For adults above the age of 65 years, LSS becomes the most common indication for spinal surgery [3].

The treatment option for LSS patients includes the conservative approaches and surgical treatment [5]. The conservative intervention comprises physical therapy, exercise, acupuncture, braces and pharmacological therapy [6]. None of these conservative approaches alter the process of disease progression, so no definite long-term effectiveness of these intervention has been reported [7]. The surgical intervention includes the decompression surgery with or without fusion and the spinal instrumentation in the form of interspinous spacers [2, 8]. And 21% of patients tend to receive surgical treatment within 3 years of the LSS diagnosis [9]. Compared with the invasive decompression surgery, the implantation of interspinous spac-

Comparison between superior and X-Stop for moderate LSS patients

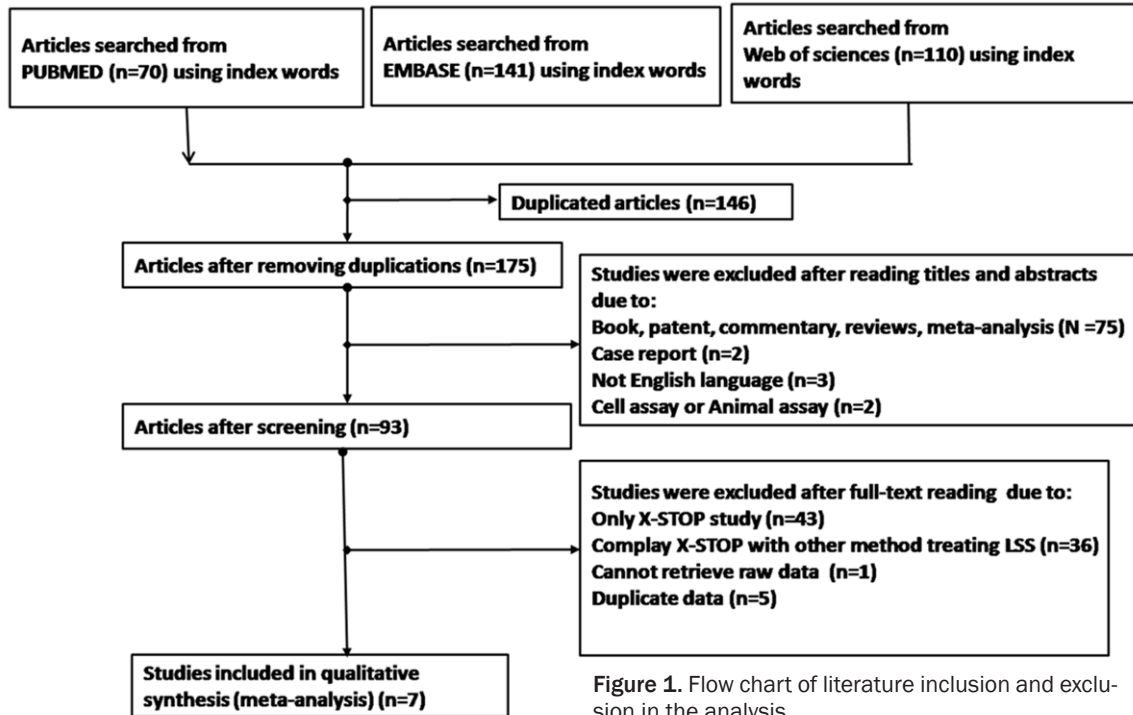


Figure 1. Flow chart of literature inclusion and exclusion in the analysis.

ers is a relatively new and less invasive treatment option for LSS patients to limit spinal extension and therefore to relieve patients' symptoms [9-11]. The surgical procedures with interspinous spacers have grown markedly over the past few years [11]. The X-Stop device, which is the first approved implant of its kind by Food and Drug Administration (FDA) to relieve symptoms of LSS, is the most widely used interspinous spacer for individuals with neurogenic intermittent claudication secondary to LSS [12, 13]. The Superior interspinous spacer, a low profile device, was also approved by FDA for commercial distribution in the United States on May 20, 2015 for the treatment of neurogenic intermittent claudication resulting from LSS [14, 15].

Conflicting results about the improvement of clinical outcomes in moderate LSS patients treated with the Superior or X-Stop interspinous spacer have been reported. Data from a prospective study inferred that for patients with moderate LSS, there was significant difference in the improvement of Zurich Claudication Questionnaire (ZCQ) patient satisfaction score and Visual Analog Scale (VAS) back pain after treatment between the Superior and X-Stop interspinous spacers, whereas no significant

difference in the improvement of VAS leg pain and Oswestry Disability Index (ODI) was detected between the two spacers [9]. However, data from a randomized controlled trial (RCT) study, published in 2015, demonstrated contradictory results [16]. In this setting, we searched the related literatures and conducted the present meta-analysis to appraise the difference in the improvement of clinical outcomes for patients with moderate LSS between the Superior and X-Stop interspinous spacers. The difference in the incidence of adverse events between the two groups was also evaluated in our study.

Materials and methods

Search strategy

The literature retrieval was performed using multiple databases including PubMed, EMBASE and Web of science from the inception up to February 23, 2016. Terms used in our search included: "Lumbar Spinal Stenosis" OR "Lumbar vertebral canal stenosis" OR "Lumbar stenosis" OR "narrow lumbar canal" AND (x-stop OR Interspinous spacer) AND (Minimally Invasive OR superior). The reference lists of reviewed articles were examined manually to identify additional related literatures. We eliminated duplicates.

Comparison between superior and X-Stop for moderate LSS patients

Table 1. The characteristics of included studies

First author	Year	Study design		LSS	Detailed information of treatment		Number of patients (Superior/X-Stop)	ZCQ	ODI	VAS	Adverse events	Follow-up
		Randomized	Prospective		Superior,	X-Stop						
E. Block	2013	Y	Y	Moderate LSS which failed to respond to conservative care	Vertiflex, San Clemente, CA	Medtronic, Memphis, TN	75/70	Y	Y	Y	-	1.5 years
Larry E. Miller	2012	Y	Y	Moderate LSS	Vertiflex, Inc., San Clemente, CA, USA	Medtronic, Inc., Sunnyvale, CA	80/86	Y	Y	Y	Y	0.5 year
Thomas Haley	2012	Y	Y	Moderate LSS who failed at least 6 months of nonsurgical management	Vertiflex, Inc., San Clemente, CA	-	51/57	Y	Y	Y	-	1 year
Thomas R. Haley	2012	Y	Y	Moderate LSS	-	-	51/57	Y	Y	Y	-	1 year
Vikas V. Patel	2014	Y	Y	Moderate LSS	VertiFlex, Inc., San Clemente, CA, USA	Medtronic, Inc., Sunnyvale, CA, USA	123/127	Y	Y	Y	Y	2 years
Vikas V. Patel	2015	Y	Y	Moderate LSS	Vertiflex Inc., San Clemente, CA	Medtronic Inc., Minneapolis, MN	190/201	Y	Y	Y	Y	2 years
Vikas V Patel	2015	Y	Y	Moderate LSS	-	-	190/201	Y	Y	Y	-	3 years

Y: yes; -: not mentioned.

Comparison between superior and X-Stop for moderate LSS patients

Inclusion and exclusion criteria

The inclusion criteria were as follows: (1) studies regarding to the efficacy and safety of the Superior and X-Stop interspinous spacers; (2) studies in which all the participants were moderate LSS patients; (3) prospective studies; (4) RCT studies. The exclusion criteria were defined as: (1) studies only related to the Superior or X-Stop interspinous spacer; (2) studies without sufficient reported data to determine an estimate of the relevant parameter; (3) some literatures types such as expert opinions, case reports, communications and news.

Data extraction

Two investigators independently assessed the eligibility of each potentially included study based on the above predefined inclusion and exclusion criteria. The discrepancies between the two investigators were resolved through a consensus discussion. Collected data included the name of the first author, publication date, study design, detailed information of each treatment, the number of patients in Superior and X-Stop interspinous spacer groups, respectively, clinical outcomes, adverse events and the follow-up duration.

Statistical analysis

As the previous related studies, we used the ZCQ for the measurement of patient satisfaction, VAS for the back and leg pain and ODI for the back specific functional disability to estimate the clinical outcomes after surgical treatment for patients with moderate LSS [17-21]. The STATA 12 software (STATA Corp LP, College Station, Texas, United States) was used to complete the meta-analysis. We firstly assessed the between-study heterogeneity by I^2 statistics. If the I^2 was less than 50%, revealing no significant statistical heterogeneity among studies, the Inverse-Variance (I-V) fixed-effects model was selected to obtain the Standardized Mean Difference (SMD) and corresponding 95% confidence interval (CI) for continuous variables, whereas the Mantel-Haenszel (M-H) fixed-effects model was introduced to compute the Risk Ratio (RR) and its 95% CI for dichotomous variables. In the presence of heterogeneity ($I^2 > 50%$), the DerSimonian and Laird (D-L) random-effects model was selected to calculate the SMD/RR and the corresponding 95% CI. The forest plots were constructed to illustrate the results of SMD or RR for each param-

eter. We used the Begg's test to evaluate the publication bias, and the Egger's test was adopted for further assessment. All statistical tests were two-sided and the value of P less than 0.05 was considered statistical significant.

In the meta-analysis, the data in X-Stop group (control) were served as reference. The data related to alterations of ZCQ, VAS back pain, VAS leg pain and ODI in both Superior (case) and X-Stop groups were collected and extracted to calculate the SMD with its corresponding 95% CI for each parameter. A SMD > 0 infers that the improvement of a parameter in Superior group is larger than that in X-Stop group. The data about the adverse events were collected and extracted for the calculation of RR with the corresponding 95% CI. A RR > 1 signifies that the occurrence rate of adverse events in Superior group is higher than that in X-Stop group.

Results

Study characteristics

A total of 321 literatures were generated after the initial search, among which 70 from PubMed, 141 from EMBASE, 110 from Web of sciences. We excluded 146 duplicated literatures with the remaining for further assessment. After screening the title and abstract, 93 potentially related literatures were identified for full-text reading, among which 7 studies satisfied our inclusion criteria. The flow chart of the literature inclusion and exclusion was described in **Figure 1**. The characteristics of the eligible studies were displayed in **Table 1**.

Evaluation of the difference in the improvement of ZCQ between the superior and X-Stop interspinous spacers for patients with moderate LSS

The patient satisfaction was measured by ZCQ, and there were 6 eligible studies included for the analysis. The results were shown in **Table 2**. The fixed-effects model was used to calculate the SMD and 95% CI for ZCQ due to the small heterogeneity ($I^2 = 37.10%$). The SMD was larger than 0 (SMD = 0.242, 95% CI: 0.127-0.357, **Figure 2**), and the value of p was lower than 0.05 ($P < 0.001$), which suggested that significant difference was found in the improvement of ZCQ after treatment between the Superior

Comparison between superior and X-Stop for moderate LSS patients

Table 2. Summary SMDs and 95% CI in the analysis

Study	SMD	Lower Limit	Upper Limit	P (SMD)	I ²	P (Heterogeneity)	P (Begg's Test)	P (Egger's test)
ZCQ	0.242	0.127	0.357	<0.001	37.10%	0.159	1.000	0.743
VAS back pain	0.147	0.032	0.263	0.012	68.80%	0.007	1.000	0.272
VAS leg pain	0.099	-0.113	0.312	0.361	68.00%	0.008	1.000	0.920
ODI	0.016	-0.172	0.205	0.865	59.30%	0.031	0.133	0.024

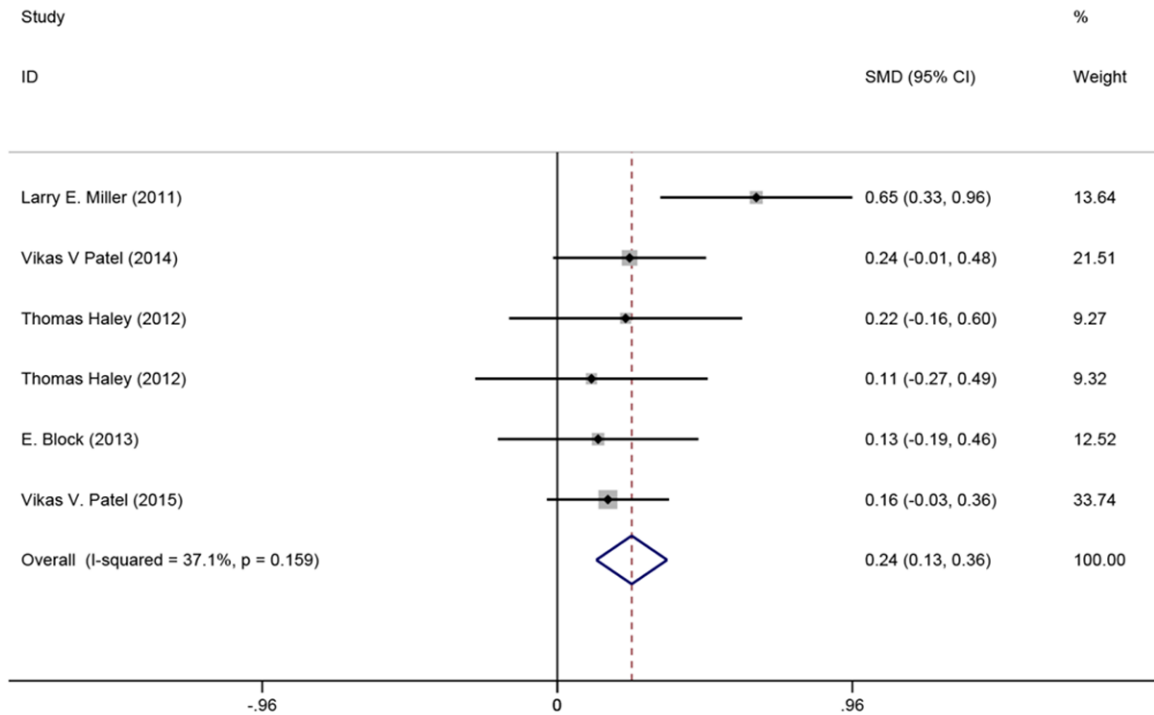


Figure 2. Forest plot of study evaluating the difference in the improvement of ZCQ between the Superior and X-Stop interspinous spacers for patients with moderate LSS.

and X-Stop, and the improvement of ZCQ in patients receiving Superior was significantly larger than that in patients implanted with X-Stop after surgery.

Evaluation of the difference in the improvement of VAS back and leg pain between the Superior and X-Stop interspinous spacers for patients with moderate LSS

As for the VAS back pain, 6 included studies were incorporated for the analysis, and the results were exhibited in **Table 2**. The I² was 68.8%, and the random-effect model was chosen to compute the SMD and 95% CI for VAS back pain. The SMD was 0.147 with the 95% CI ranged from 0.032 to 0.263 (**Figure 3**), and there was significant difference in the improvement of VAS back pain after treatment between

the Superior and X-Stop (P = 0.012), demonstrating that the improvement of VAS back pain severity in patients treated with Superior was significantly larger than that in patients receiving X-Stop after surgery.

With respect to the VAS leg pain, there were 6 eligible studies, and the results were summarized in **Table 2**. The heterogeneity among the included studies was large (I² = 68.00%), and the random-effects model was applied to yield the corresponding SMD and 95% CI for VAS leg pain. Although the SMD was larger than 0 (SMD = 0.099, 95% CI: -0.113-0.312, **Figure 4**), the value of p was 0.361. The results implied that for patients with moderate LSS, there was no significant difference in the improvement of VAS leg pain severity between the Superior and X-Stop after treatment.

Comparison between superior and X-Stop for moderate LSS patients

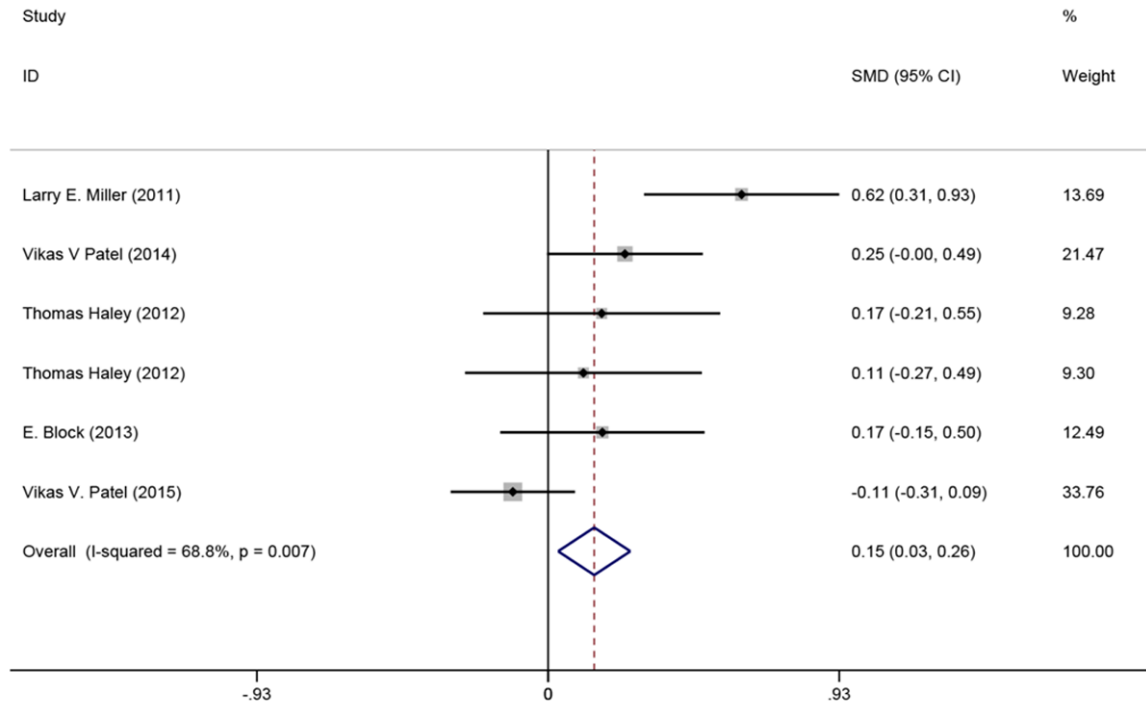


Figure 3. Forest plot of study assessing the difference in the improvement of VAS back pain between the Superior and X-Stop interspinous spacers for patients with moderate LSS.

Evaluation of the difference in the improvement of ODI between the superior and X-Stop interspinous spacers for patients with moderate LSS

The ODI was considered as the parameter of back specific functional disability, and there were 6 eligible studies for the analysis. The results were recorded in **Table 2**. Significant heterogeneity was observed among the 6 incorporated studies ($I^2 = 59.30\%$), so we used the random-effect model to obtain the SMD and its 95% CI for ODI. The SMD was larger than 0 (SMD = 0.016, 95% CI: -0.172-0.205, **Figure 5**) with the P larger than 0.05 ($P = 0.865$), inferring that for patients with moderate LSS, no significant difference in the improvement of ODI was detected between the Superior and X-Stop after treatment.

Evaluation of the difference in the occurrence rate of adverse events between the Superior and X-Stop interspinous spacers for patients with moderate LSS

In terms of the adverse events, considering the small heterogeneity inter-included studies ($I^2 = 37.80\%$), the fixed-effects model was selected

to produce the RR and its 95% CI. The results were summarized in **Table 3**. Despite the RR was larger than 1 (RR = 1.056, 95% CI: 0.998-1.118, **Figure 6**), the value of p was larger than 0.05 ($P = 0.059$). The results displayed that for patients with moderate LSS, no significant difference in the adverse events was found between the Superior and X-Stop after treatment.

Publication bias

We examined the publication bias using the Begg's and Egger's tests, and the results were recorded in **Tables 2** and **3**. The values of P in both Begg's and Egger's tests were larger than 0.1 for ZCQ, VAS back pain, VAS leg pain and adverse events, suggesting that there was no significant publication bias in these analyses. For ODI, the value of P in Begg's test was larger than 0.1, which indicated that no significant publication bias was found in the analysis, even if the value of P in Egger's test was less than 0.1.

Discussion

The current study, to our knowledge, is the first meta-analysis to estimate the difference in the

Comparison between superior and X-Stop for moderate LSS patients

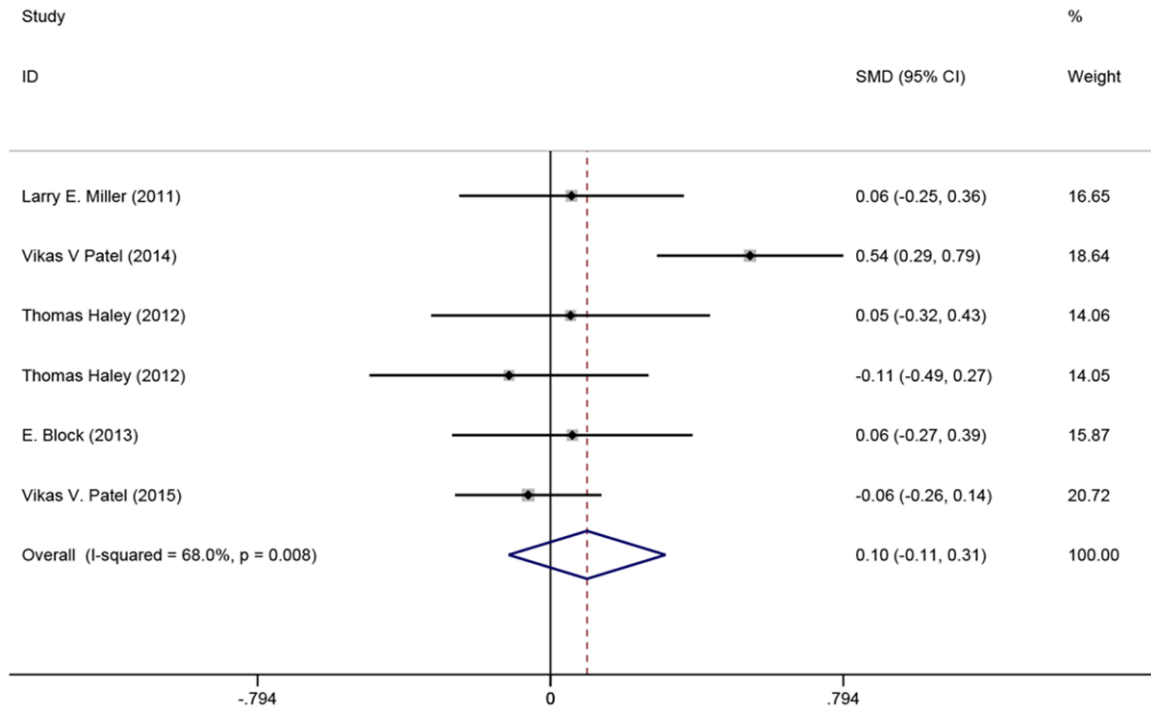


Figure 4. Forest plot of study appraising the difference in the improvement of VAS leg pain between the Superior and X-Stop interspinous spacers for patients with moderate LSS.

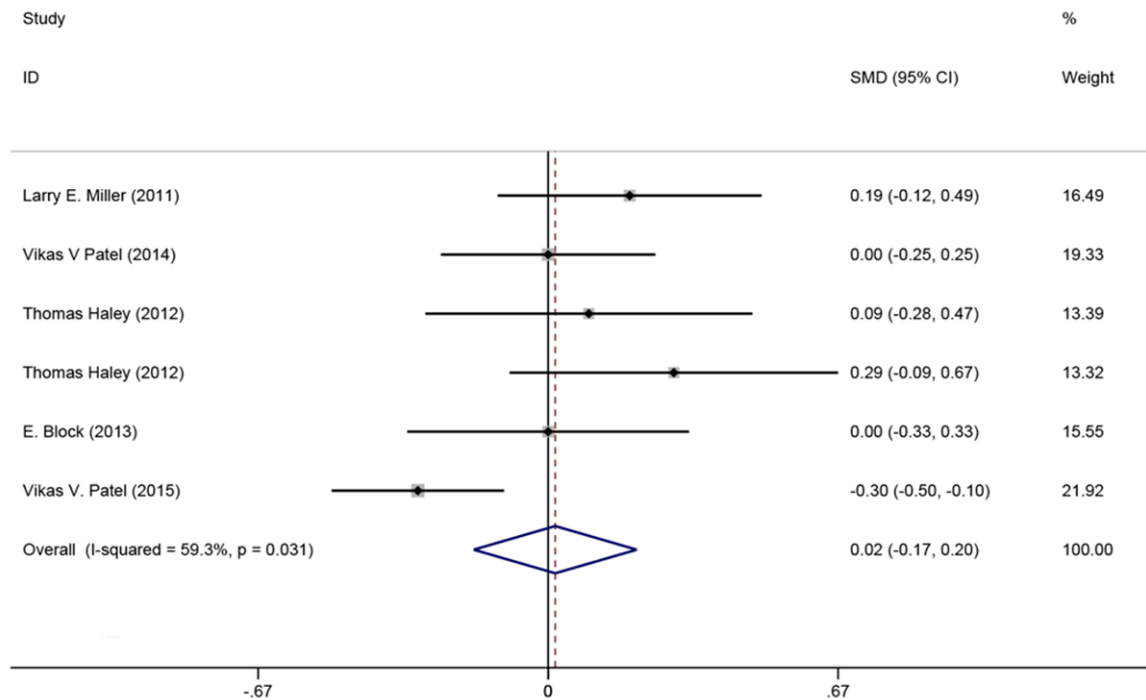


Figure 5. Forest plot of study estimating the difference in the improvement of ODI between the Superior and X-Stop interspinous spacers for patients with moderate LSS.

efficacy and safety for moderate LSS patients after treatment between the Superior and

X-Stop spacers. In our study, we used the indices of clinical outcomes including the ZCQ, VAS

Comparison between superior and X-Stop for moderate LSS patients

Table 3. Summary RR and its 95% CI in the analysis

Study	RR	Lower Limit	Upper Limit	P (RR)	I ²	P (Heterogeneity)	P (Begg's Test)	P (Egger's test)
Adverse events	1.056	0.998	1.118	0.059	37.80%	0.200	0.296	0.255

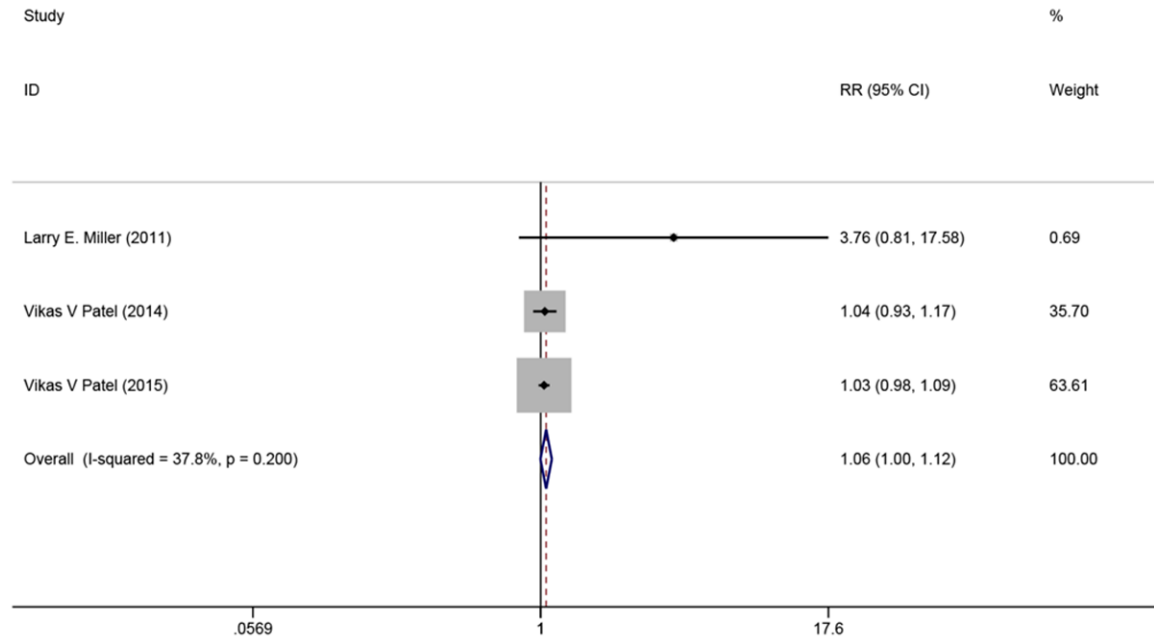


Figure 6. Forest plot of study assessing the difference in the occurrence rate of adverse events between the Superior and X-Stop interspinous spacers for patients with moderate LSS.

back pain, VAS leg pain and ODI as the parameter of efficacy. The occurrence rate of adverse events was regarded as the index of safety. Our results showed that significant difference in the improvement of ZCQ and VAS back pain was detected between the two spacers, and patients receiving Superior had significantly higher patient satisfaction and larger reduction of VAS back pain severity than those treated with X-Stop after surgery; whereas there was no significant difference in the improvement of VAS leg pain and ODI, and the occurrence rate of adverse events between the two spacers after treatment.

LSS, usually caused by spinal degeneration, is a clinical syndrome manifesting as pain in the buttocks or lower extremities, with the presence or absence of back pain [2, 3]. It may be congenital or acquired [22]. The symptoms of LSS may be attributed to the compression in central canal or lateral recess, elevated epidural pressure, venous congestion, or inflamma-

tion-induced nerve root excitation [2]. Over 200,000 adults suffer from substantial pain and disability ascribed to LSS in the United States [3]. For the treatment of LSS, the non-surgical therapy, which is usually recommended to patients before surgery, is widely used to relieve pain and improve physical function for early stage of LSS [23]. However, the benefits from conservative treatment are debating, and a prospective study revealed that although both the conservative and surgical approaches could relieve pain for patients, only the surgical treatment could improve nocturnal leg cramps associated with spinal nerve compression for LSS patients [24]. A review study also concluded that for LSS patients unresponsive to conservative care for 3 to 6 months, the surgical treatment was more effective, when compared with the continued non-operative therapy [2].

For patients with moderate LSS, there is no widely acceptable safe and effective therapy, and the conservative treatment only provides

Comparison between superior and X-Stop for moderate LSS patients

partial relief for the symptoms, while the invasive decompression surgery is not suitable for all patients with different severity of symptoms [14, 25]. Interspinous spacers, offering a less-invasive alternative, address the therapeutic gap between the conservative treatment and the invasive decompression surgery for patients with moderate LSS [25, 26]. Compared with other surgical approaches, the implantation of interspinous spacer has lower neural injury risk, earlier intervention in the disease process and greater preservation of anatomical structures for patients with moderate LSS [7]. The Superior and X-Stop are currently the two only types of FDA-approved interspinous spacers for the treatment of neurogenic claudication secondary to LSS [15, 16]. In our study, we compared the improvement of clinical outcomes and the occurrence rate of adverse events between the Superior and X-Stop interspinous spacers for patients with moderate LSS after surgery. Our results revealed that compared with patients receiving X-Stop interspinous spacer, those treated with Superior interspinous spacer had significantly higher patient satisfaction and larger reduction of back pain severity after treatment. We inferred from our results that for moderate LSS patients, the clinical outcomes of Superior interspinous spacer was more favorable than those of X-Stop interspinous spacer.

ZCQ is a useful assessment tool specific to LSS that consists of symptom severity domain, physical function domain and patient satisfaction domain [27, 28]. In our meta-analysis, we only comprehensively evaluated the patient satisfaction using the ZCQ patient satisfaction scales, since there was insufficient data to estimate the other two domains after surgery. The ZCQ patient satisfaction scales include six questions, and the patient satisfaction is determined by averaging the scores of these questions [29, 30]. The scores of each question range from a score of 1 to a score of 4, and a lower score indicates a higher patient satisfaction [30]. Our results demonstrated that compared with patients implanted with X-Stop interspinous spacer, those receiving Superior were more likely to obtain a higher patient satisfaction after surgery.

VAS, which is a simple tool to measure the subjective symptoms, has been frequently used to

assess the chronic and acute pain intensity since 1966 [31]. The VAS is easily administered by marking a 100-mm line anchored with terms representing the extremes of pain severity [32]. In this meta-analysis, we used the VAS to estimate the back and leg pain for moderate LSS patients, and our results signified that compared with patients receiving X-Stop interspinous spacer, those treated with Superior were more likely to have a larger reduction in the back pain severity, while the improvement of leg pain in the two interspinous spacers was similar after treatment.

ODI, measuring the pain-related disability, is commonly considered as a parameter of primary outcome for back pain research [8, 20, 33]. The ODI questionnaire includes 10 questions involved in mobility and social life due to low back pain. A score of 0 indicates a condition of not disabled at all, whereas a score of 100 signifies a condition of completely disabled [18, 34]. In our study, we used the ODI to estimate the back specific functional disability, and our results showed that there was similar improvement of back specific functional disability in the two interspinous spacers after treatment.

The Superior and X-Stop interspinous spacers have been proven to effectively improve the clinical outcomes for patients with moderate LSS [25]. The mechanism of action for the implantation of Superior and X-Stop is similar, and the two interspinous spacers are implanted through a posterior incision and demand initial distraction [16]. Our results showed that patients receiving Superior had more favorable clinical outcomes than those receiving X-Stop interspinous spacer after surgery, which might be partly explained by the difference in device design and surgical implantation technique between the two spacers. Compared with Superior, the X-Stop requires much greater surgical exposure resulting in larger blood loss and longer hospital stay [16]. Furthermore, the occurrence of dislodgements and migrations ascribed to the slender wings of X-Stop spacers and open process of the X-Stop implantation may also be partly responsible for the more favorable clinical outcomes of Superior interspinous spacer.

Although we have put our best efforts into avoiding potential bias, there are still several

Comparison between superior and X-Stop for moderate LSS patients

limitations of the meta-analysis. First, the follow-up periods in all included studies are not exactly the same, which may cause bias for our results. And with more related studies available, subgroup-analysis stratified by different follow-up periods would be performed to have more precise and accurate estimations. Second, we have not taken the unpublished studies into consideration.

In summary, pooled data from randomized clinical trials suggest that compared with moderate LSS patients receiving X-Stop interspinous spacer, those implanted with Superior are more likely to obtain higher patient satisfaction and larger reduction in the back pain severity after surgery. And for patients who have to receive the implantation of interspinous spacers, the Superior device is a more reasonable treatment option.

Disclosure of conflict of interest

None.

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Comparison between superior and X-Stop for moderate LSS patients

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