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Dynamic Posterior Stabilization versus Posterior Lumbar Intervertebral Fusion: A Matched Cohort Study Based on the Spine Tango Registry

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Keywords

dynamic stabilization – fusion – degenerative spine – disease – propensity score-based – matching – registry

2 Tables and 1 Figure

Table 1: Patient characteristics in matched and nonmatched patients

Table 2: Outcome measures

Figure 1: Study flowchart

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ABSTRACT

Purpose

The primary aim of dynamic stabilization is to stabilize the spine and preserve function without overstressing adjacent segments, which is a potential risk of fusion surgery. However, direct comparative analyses of the two approaches are still limited, and little is known about the association of patient-reported outcomes with these treatment options.

Objective

To compare the clinical outcomes of dynamic posterior stabilization using the DSS Stabilization System (Paradigm Spine, LLC, New York, New York, United States) versus posterior lumbar intervertebral fusion (PLIF) based on data from a spine registry. We hypothesized that patient-reported outcomes of DSS are not inferior to those of PLIF.

Methods

We identified 202 DSS and 269 PLIF patients with lumbar degenerative disease with a minimum 2-year follow-up. A 1:1 propensity score–based matching was applied to balance the groups for various patient characteristics. The primary outcome was the change in the patient-reported Core Outcome Measures Index (COMI; a 0–10 scale) score.

Results

The matching resulted in 77 DSS-PLIF pairs (mean age: 67 years; average COMI follow-up: 3.3 years) without residual significant differences in baseline characteristics. The groups showed no difference in improved COMI score ($p = 0.69$), as well as in back ($p = 0.51$) and leg pain relief ($p = 0.56$), blood loss ($p = 0.12$), and complications ($p > 0.15$). Fewer repeat surgeries occurred after DSS ($p = 0.01$). The number of repeat surgeries per 100 observed person-years was 0.8 and 2.9 in DSS and in PLIF

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patients, respectively. Furthermore, shorter surgery time ($p < 0.001$) and longer hospital stays ($p = 0.03$) were observed for DSS cases.

Conclusion

In a midterm perspective, DSS may be a viable alternative to PLIF because both therapies result in similar COMI score improvement. Advantages of DSS may be shorter duration of surgery and fewer repeat surgeries. However, more than half of DSS patients did not find a match with a PLIF patient, suggesting that the patient profiles may be different. Further multicenter studies are needed to better understand the most appropriate indication for each therapy.

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INTRODUCTION

Spinal fusion is considered the gold standard therapy for a variety of pathologic conditions.[1,2] It is particularly recommended in patients with dominant back pain for whom decompression surgery alone is insufficient.[3] However, fusion surgery is associated with several undesirable effects such as accelerated degeneration of the adjacent segments and persistent back pain. Biomechanical changes after intervertebral fusion, such as increased mobility, increased facet loading, and increased intradiskal pressure in the segments, may be responsible for these side effects.[4]

To minimize the risk of adjacent segment degeneration, an interest arose in alternative motion-preserving techniques that restore intersegmental stability and motion in a controlled way. The primary aim of dynamic systems is to stabilize the operated segments while preserving a predefined mobility in all motion planes, thus avoiding hypermobility of the adjacent segments. Various devices have been explored and their results reported. However, the evidence whether dynamic stabilization is more beneficial than spinal fusion remains debatable.[5–8]

In 2008, the DSS Stabilization System (Paradigm Spine, LLC, New York, New York, United States) was introduced. The design for this pedicle screw based dynamic posterior stabilization device was developed with implemented stiffness parameters delineated in a validated finite element model.[9–12] The first results of consecutive case series demonstrated good and stable clinical outcomes.[13–15] However, no comparative evidence on the effectiveness of this device is available to date.

The objective of this study was to compare the short- and midterm outcomes of dynamic posterior stabilization using DSS with posterior lumbar intervertebral fusion (PLIF) in patients with lumbar degeneration spine disease based on data from a large international spine registry. We hypothesized that patient-reported outcomes of DSS are not inferior to those of PLIF.

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MATERIALS AND METHODS

Ethics approval was obtained through the German arm of the Spine Tango registry from the ethics committee of the University Hospital Cologne (No. 09–182), where the German Spine Tango server module is located.

Study design

This was a retrospective analysis of prospectively collected data within the Spine Tango registry.

Spine Tango Registry

Spine Tango is a voluntary registry under the auspices of EUROSPINE, the Spine Society of Europe, hosted at the Swiss RDL—Medical Registries and Data Linkage of the Institute for Social and Preventive Medicine of the University of Bern, Switzerland.[16] The registry captures physician-based primary and follow-up data on surgical treatments for spinal disorders. Detailed information on pathology, perioperative characteristics, surgical measures, and complications is captured with the surgery data collection form. The surgery form is also used to document repeat surgeries. In addition, the registry documents patient-reported outcomes using the Core Outcome Measures Index (COMI) questionnaire.[17] The COMI is a short self-administered outcome instrument consisting of seven questions to evaluate the five dimensions of pain, back-related function, symptom-specific well-being, general quality of life, and disability (social and work). Two pain graphical rating scales (GRS 0–10 points; 0, no pain; 10, the worst imaginable pain) capture back and leg pain, and all other items use a 5-point Likert scale. For the summary score, the average of the scores for all five dimensions (each transformed to 0–10; 0, the best score value; 10, the worst score value) is calculated.

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Study Population

The registry database was screened in August 2016 for patients with lumbar degenerative disease treated either with dynamic posterior stabilization using DSS or PLIF. All DSS and PLIF surgeries were performed in combination with decompression. In the PLIF group, all patients had a pedicle screw with rod fixation combined with a cage placement. These further inclusion criteria were applied: previous conservative treatment for the diagnosed pathology, not more than two previous spinal surgeries, up to three treated segments, one preoperative COMI questionnaire, and at least one postoperative COMI questionnaire available at least 2 years after surgery. If multiple follow-up COMI forms were available for a patient, the latest form was selected for analysis. The exclusion criteria were other or “additional spinal pathology” such as deformity, fracture, tumor, inflammation, infection, spondylolisthesis, and repeat surgery that was not performed on the same or adjacent level as the index surgery.

Outcome Measures

The primary outcome was the pre- to postoperative improvement in COMI score. Secondary outcomes were pre- to postoperative relief in back and leg pain, rate of repeat surgeries, surgical and general complication rates, blood loss, surgery duration, and length of hospital stay. A repeat surgery was defined as a subsequently documented surgery either on the same or an adjacent level as the index surgery.

Statistical Analysis

Patients with DSS were matched to PLIF patients based on propensity score. The propensity score method was described in detail by Rosenbaum and Rubin.[18] In brief, an individual’s propensity score is defined as the conditional probability of being exposed to DSS versus PLIF treatment, given the observed covariates. Two patients with the same propensity score have an equal estimated probability of exposure to both treatments. If one was exposed to DSS and the other to PLIF

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treatment, the exposure allocation can be considered random, conditional on the observed covariates. Therefore, there is a balance of the observed covariates between DSS and PLIF treatment after adjusting for the propensity score, and the matched patients in the groups can be considered as similar.

The individual propensity scores were obtained from a multiple logistic regression model that included the following covariates: patient age (continuous), sex (male, female), disk herniation (yes, no), spinal stenosis (yes, no), most severely affected segment (L1–L2, L3–L4, L4–L5, L5–S1), previous spinal surgery (yes, no), timing of previous conservative treatment (≤ 12 months, > 12 months), number of treated segments (1, 2–3), American Society of Anesthesiologists (ASA) score (1, 2, > 2), preoperative COMI (continuous), back pain (continuous), and leg pain (continuous) scores, and the follow-up interval in months (continuous). The propensity scores were then fed into a greedy matching algorithm for 1:1 matching, using the OneToManyMTCH SAS macro published by Parsons.[19]

The sample size calculation centered on the hypothesis of noninferiority of the COMI score change. We estimated the mean change in COMI score to be 3.8 points with a standard deviation of 2.8 points,[20] and we assumed a very low correlation of COMI score between the matched pair of r = 0.05. The noninferiority margin was set at the minimal clinically important change in COMI score of 2.2 points.[21] A one-sided paired test with 80% power resulted in a sample size of 25 patients per group.

For the comparison of matched pairs, the chi-square test for categorical covariates and the paired t test for continuous covariates were used. For continuous outcome, measures mean differences, and for categorical outcome, measures relative risk with 95% confidence limits (CL) were calculated. In addition, the number of repeat surgeries per 100 observed person-years (equals follow-up years) after index surgery was calculated in each group to adjust for the different average follow-up time in the groups.[22,23]

All statistical analyses were conducted using SAS v. 9.4 (SAS Institute, Inc., Cary, North Carolina, United States) with α = 0.05.

RESULTS

Study Population

The inclusion and exclusion criteria resulted in 471 patients treated with DSS (n = 202) or PLIF (n = 269) between February 2006 and April 2014 (Fig. 1). All DSS patients were treated in one clinic, and data on PLIF patients originated from 16 hospitals from six countries (Australia, Belgium, Germany, Switzerland, United Kingdom, and the United States). The clinic with DSS cases also documented 10 PLIF cases.

The matching algorithm resulted in 77 patient pairs without residual significant differences, leaving 317 nonmatched patients (Table 1). The data came from 12 hospitals representing the six countries just listed. The most frequently documented decompression types were partial facet joint resection in 16 DSS (21%) and 53 PLIF (69%) patients, flavectomy in 75 DSS (97%), and 49 PLIF (64%) patients, foraminotomy in 1 DSS (1%) and 36PLIF (47%) patients, and sequestrectomy in 10 DSS (13%) and 4 PLIF (5%) patients.

Primary and Secondary Outcomes

The outcome analysis was performed on the matched patients and is summarized in Table 2. At an average of 3.3 years postoperative in both groups, COMI score improved from 8.0 points at baseline to 4.5 points at follow-up after DSS and from 7.9 to 4.6 points after PLIF, respectively.

A surgical complication was reported in six DSS (8%) and seven PLIF (9%) patients ($p = 0.77$). A general complication was reported in no DSS and in two PLIF (3%) patients ($p = 0.15$). More than one complication was documented in two PLIF patients. In the DSS group, five incidental dural tears and one wound infection were reported. In PLIF, four incidental dural tears, two neurologic complications, one vascular lesion, one urinary tract complication, and one unspecified complication were reported.

Three repeat surgeries (4%) in DSS patients and 12 in PLIF patients (16%) (p = 0.014) took place at an average of 4.5 and 5.9 years after the index surgery (range in the DSS group: 4.4–4.7; range in the PLIF group: 2.3–9.1), respectively. The repeat surgery was on an adjacent segment in all three DSS patients and in nine PLIF patients (p = 0.071). In three remaining PLIF patients with a repeat surgery, the same segment was involved (p = 0.080). The reason for the repeat surgery in all three DSS patients was further degeneration of the affected segments. In PLIF patients, the reasons were nonunion (n = 3), further degeneration (n = 7), non-union and instability (n = 1), and a pathologic fracture (n = 1). The type of repeat surgery in the DSS group was a decompression with an extended dynamic stabilization to the adjacent segment (n = 2) and a decompression with an instrumented fusion (n = 1). In the PLIF group, decompression alone (n = 2) and decompression with an instrumented fusion (n = 10) were applied. The number of repeat surgeries per 100 observed person-years was 0.8 and 2.9 in DSS and in PLIF patients, respectively.

DISCUSSION

The main finding of this study was that patients undergoing dynamic posterior stabilization using DSS experienced an improvement in COMI score after at least 2 years of follow-up as good as patients with PLIF, which confirms our noninferiority hypothesis. In addition, DSS patients had a significantly lower rate of repeat surgeries, shorter surgery duration, and longer duration of hospital stay.

Impairment in daily life due to pain and functional limitations is one of the main indications for surgical treatment in patients with pathologic spine conditions who are unresponsive to conservative therapy. Therefore, the COMI score was chosen as the primary outcome in the study. The score incorporates several domains including functional limitations, quality of life, and pain. The COMI score improved ≥ 40% from the baseline value at a mean follow-up of 3.3 years in both groups. In addition, pain levels decreased to a similar extent. This implies that both treatment methods are effective in terms of patient perception of the treatment outcome over the midterm. Similar improvements were reported in other studies comparing other dynamic stabilization techniques with fusion surgery.[8,24]

Proponents of dynamic stabilization claim that this technique is less invasive and can potentially reduce recovery time compared with spinal fusion in the short term.[25,26] Many previous studies indicated that dynamic stabilization is more beneficial than fusion in terms of surgery duration [7,8,24,27,28] In this study, all DSS patients were operated on in < 2 hours; > 2 hours was required for most (80%) of PLIF patients. However, our analysis showed a 1 day longer hospitalization after DSS compared with PLIF. We believe this difference may be due to differences in international hospitalization guidelines and reimbursement models rather than a direct association with the postoperative morbidity of the patient.

Dynamic stabilization is expected to result in fewer repeat surgeries than a fusion surgery because dynamic stabilization is intended to prevent the overstress of adjacent segments taking place in patients with a fused spinal segment.[5] In this study, significantly fewer repeat surgeries were performed after DSS compared with PLIF in the midterm (4% versus 16%). In both groups, the main reason for repeat surgery was further degeneration of the affected segments. Studies comparing the Dynesys pedicle screw system (Zimmer Biomet, Warsaw, Indiana, United States) for dynamic stabilization with PLIF[24,27,28] or other dynamic stabilization techniques with fusion surgery[8] observed the risk for repeat surgery to range in a midterm perspective between 0% and 9% for various indications without any significant differences between groups. A systematic review of lumbar spine fusion by Phillips et al reported an overall reoperation rate of 12.5% in a pool of two 1-year, three 2-year, and one 4-year follow-up studies.[29] The slightly higher rate of revisions in our fusion group may be Explained by the fact that our patients underwent a revision on average of 5.9 years (range: 2.3–9.1 years) after the index surgery, which means that most revisions were performed 4 years after the index surgery.

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Only for adjacent segment surgery was the rate lower in the DSS group (4% versus 12%), although this difference was not significant. Similar rates were reported earlier. Lee et al reported the probability of undergoing a revision surgery for adjacent segment disease at 5.8% at 5 years and at 10.4% at 10 years after lumbar spine fusion.[30] In a systematic review of different pedicle-based dynamic stabilization techniques, Prud'homme et al found an adjacent segment degeneration rate of 3.4%; the overall revision rate was 9.4%.[6] However, the comparison of revision rates between studies is difficult due to different definitions of and indications for repeat surgeries as well as varying follow-up times. To adjust for follow-up time, we standardized the repeat surgery rate per 100 observed person-years after index surgery. This method was introduced in orthopaedics by the Australian Joint Replacement Registry and became a widely used outcome parameter in hip and knee arthroplasty. Applying this approach in our study showed a three times higher ratio of repeat surgery in the PLIF group. This means that after treatment of 10 patients, three patients can be expected to be reoperated during 10 years after PLIF and one patient after DSS.

Limitations

Some limitations of the study deserve mention. The DSS patients originated from a single treatment center and were compared with a multicenter PLIF group. The PLIF group was potentially more heterogeneous in terms of patient population and treatment technique. Furthermore, both DSS and PLIF are performed in combination with decompression, which may provide benefits independently of the type of stabilization. A recent randomized controlled trial among patients with lumbar spinal stenosis found similar clinical outcomes between decompression surgery alone and decompression surgery plus fusion surgery.[31] However, different approaches to the surgical interventions might limit the findings. Other studies revealed that simple decompression surgery may be insufficient in patients with dominant back pain (> 5 points) at baseline,[3,32,33] which was most of our study population. Although we matched on individual propensity scores, only the observed characteristics can be balanced this way. An influence of unobserved factors is possible but remains unknown.

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Because Spine Tango is an unmonitored voluntary registry, underreporting of complication and revision surgeries cannot be excluded, and differences in reporting may exist between centers. However, a comparison of complication rates between Spine Tango and other studies and databases showed comparable or even higher rates in Spine Tango, which suggests credible reporting in this registry.[20] Further, 60% of DSS patients could not be matched, implying they were rather different from the eligible PLIF patients and that DSS and PLIF are not always used to treat the same patient population. Finally, unlike fusion, the major concern for pedicle-based stabilization systems is screw loosening.[34] Although no such case was observed in this study, radiographic evaluations and complications without repeat surgery were not documented.

CONCLUSIONS

Patient-reported outcome 3.3 years after DSS is not inferior to PLIF. DSS may be a viable alternative to PLIF for lumbar degenerative disease and may have potential advantages of shorter surgery time and a reduced risk for repeat surgeries. Further multicenter studies are needed to better understand the most appropriate indication for each therapy.

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TABLE

Table 1

Patient characteristics in matched and nonmatched patients. ASA, American Anesthesiologist Association; COMI, Core Outcome Measures Index; PLIF, posterior lumbar intervertebral fusion.

Note: Mean ± standard deviation are shown for continuous covariates.

	Matched patients (*n* = 154)			Nonmatched patients (*n* = 317)		
Patient characteristics	DSS (*n* = 77)	PLIF (*n* = 77)	*p*	DSS (*n* = 125)	PLIF (*n* = 192)	*p*
Patient age, y	67 ± 12	67 ± 8	0.87	69 ± 11	62 ± 13	< 0.001
Females, %	64	58	0.51	42	65	< 0.001
Disk herniation, %	13	9	0.44	0	31	< 0.001
Spinal stenosis, %	83	80	0.54	90	35	< 0.001
Previous spinal surgery, %	23	23	1.00	5	41	< 0.001
Conservative treatment > 12 mo, %	43	49	0.42	28	60	< 0.001
Segment						
L1–L2 to L3–L4, %	31	22		22	27	< 0.001
L4–L5, %	61	71	0.38	77	40	
L5–S1, %	8	7		1	33	
Bi- or tri-segment surgery, %	30	31	0.86	6	65	< 0.001
ASA score, %						
1	22	21		31	20	< 0.001
2	65	65	0.96	63	48	
> 2	13	14		6	32	
Back pain at baseline, points	6.6 ± 2.2	6.3 ± 2.9	0.41	5.8 ± 3. 0	6.7 ± 2.3	0.003
Leg pain at baseline, points	6.8 ± 2.4	6.7 ± 2.8	0.85	7.2 ± 2.4	6.1 ± 2.78	< 0.001
COMI score at baseline, points	8.0 ± 1.3	7.9 ± 1.8	0.67	8.1 ± 1.6	7.8 ± 1.6	0.213
Follow-up interval, y	3.3 ± 0.8	3.3 ± 1.7	0.84	3.2 ± 0.8	3.8 ± 1.5	0.001

Table 2

Outcome measures. CL, confidence limit; COMI, Core Outcome Measures Index; PLIF, posterior lumbar intervertebral fusion.

Note: Mean ± standard deviation are shown for continuous outcome measures. For continuous outcome measures, mean differences and for categorical outcome measures, relative risk ratios with 95% CLs were calculated.

	DSS (*n* = 77)	PLIF (*n* = 77)	Effect (95% CL)	Comparison, *p* value
Primary outcome				
COMI score improvement, points	3.4 ± 2.7	3.2 ± 3.0	− 0.2 (− 1.1 to 0.7)	0.69
Secondary outcomes				
Back pain relief, points	2.9 ± 2.7	2.6 ± 3.1	− 0.3 (− 1.3 to 0.6)	0.51
Leg pain relief, points	3.1 ± 3.1	2.8 ± 3.7	− 0.3 (− 1.4 to 0.8)	0.56
Surgical complication, %	8	9	0.9 (0.3–2.4)	0.77
General complication, %	–	3	–	0.15
Blood loss, %				
< 500 mL	78	68		0.12
500–1,000 mL	22	24	0.7 (0.4–1.2)	
> 1,000 mL	–	8		
Surgery time, %				
< 1 h	26	1		< **0.001**
1–2 h	74	19	0.8 (0.7–0.9)	
> 2 h	–	80		
Length of hospital stay, d	11 ± 6	10 ± 5	− 1.0 (− 3.5 to − 0.2)	**0.03**
Repeat surgery, %	4	16	0.3 (0.1–0.9)	**0.01**

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FIGURE

Figure 1

Study flowchart.

ASA, American Anesthesiologist Association; COMI, Core Outcome Measures Index; PLIF, posterior lumbar intervertebral fusion.