Lumbar dynamic pedicle-based stabilization versus fusion in degenerative disease: a multicenter, double-blind, prospective, randomized controlled trial

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OBJECTIVE Fusion is the standard of treatment for degenerative lumbar symptomatic instabilities. Dynamic stabilization is a potential alternative, with the aim of reducing pathological motion. Potential advantages are a reduction of surgical complexity and morbidity. The aim of this study was to assess whether dynamic stabilization is associated with a higher degree of functional improvement while reducing surgical complexity and thereby surgical duration and perioperative complications in comparison with lumbar fusion.

METHODS This was a multicenter, double-blind, prospective, randomized, 2-arm superiority trial. Patients with symptomatic mono- or bisegmental lumbar degenerative disease with or without stenosis and instability were randomized 1:1 to instrumented fusion or pedicle-based dynamic stabilization. Patients underwent either rigid internal fixation and interbody fusion or pedicle-based dynamic stabilization. The primary endpoint was the Oswestry Disability Index (ODI) score, and secondary endpoints were pain, health-related quality of life, and patient satisfaction at 24 months.

RESULTS Of 293 patients randomized to fusion or dynamic stabilization, 269 were available for analysis. The duration of surgery was significantly shorter for dynamic stabilization versus fusion, and the blood loss was significantly less for dynamic stabilization (380 ml vs 506 ml). Assessment of primary and secondary outcome parameters revealed no significant differences between groups. There were no differences in the incidence of adverse events.

CONCLUSIONS Dynamic pedicle-based stabilization can achieve similar clinical outcome as fusion in the treatment of lumbar degenerative instabilities. Secondary failures are not different between groups. However, dynamic stabilization is less complex than fusion and is a feasible alternative.

Clinical trial registration no.: NCT01365754 (ClinicalTrials.gov)

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KEYWORDS lumbar degenerative instability; spondylolisthesis; lumbar stenosis; dynamic stabilization; lumbar fusion
ment degeneration (radiological as well as symptomatic), potentially resulting in secondary surgery.

An alternative to rigid instrumented fusion is dynamic stabilization by pedicle-based constructs, that is, a dynamic, partially mobile construct using pedicle screws to reduce painful pathological motion while maintaining some residual nonpathological motion.1,2 While targeting patients’ clinical symptoms by reduction of segmental movement, this technique is thought to be associated with reduced surgical complexity, as an interbody approach is not necessary. It is a faster, less-invasive surgical procedure with a reduced rate of secondary progressive adjacent-segment degeneration, as residual motion of the index segment should reduce biomechanical forces at the adjacent segment in comparison with fusion. Different systems for pedicle-based dynamic stabilization and techniques of dynamization or motion preservation are approved for degenerative instabilities in many countries. So far, noncontrolled case series assessing clinical outcomes of dynamic pedicle-based stabilization have reported clinical results that are similar to those of fusion.3–6 One study compared lumbar pedicle-based nonfusion with rigid fusion within a small, prospective, randomized study and found no differences in clinical outcome.7 So far, no high-quality study has assessed whether dynamic pedicle-based stabilization is superior to fusion with regard to patient symptoms. Therefore, the aim of this study was to assess whether dynamic pedicle-based lumbar stabilization is associated with the same degree of functional improvement, reduced surgical complexity and duration, and perioperative complications as lumbar fusion for mono- or bisegmental degenerative instability.

Methods

The study followed the World Medical Association’s Declaration of Helsinki and was approved by the local responsible ethics committee of each participating center. The trial was registered at ClinicalTrials.gov (identifier no. NCT01365754).

Study Design and Treatments

A multicenter, double-blind, prospective, randomized, 2-arm superiority trial was designed to compare lumbar spinal fusion with dynamic lumbar spinal stabilization for patients with degenerative instabilities with or without spinal stenosis. Patients fulfilling the inclusion and exclusion criteria (Table 1) were randomized to undergo mono- or bisegmental lumbar fusion or dynamic stabilization with or without decompression. The indication for fusion or dynamic stabilization and the necessity of additional decompression of the spinal canal for stenosis were based on clinical data, MRI findings, and flexion-extension radiographs of the lumbar spine. The presence of 1) ≥ 5 mm spondylolysis or segmental instability of ≥ 3 mm or ≥ 10° on flexion-extension imaging, or 2) predominant back pain with Modic changes was defined as the indication for fusion or stabilization.

Treatment assignment was performed at the study site using randomization envelopes. Randomization was 1:1, stratified by center and need for decompression, with a block size of 2 due to the multitude of study centers.

Patients randomized to fusion underwent mono- or bisegmental rigid pedicle-based fixation and interbody fusion with a PEEK cage via transfemoral lumbar interbody fusion or posterior lumbar interbody fusion techniques, with or without additional posterolateral fusion and decompression of the spinal canal where necessary. Patients randomized to dynamic stabilization underwent mono- or bisegmental dynamic stabilization with the pedicle-based dynamic stabilization system cosmoMIA (ulrich medical GmbH & Co. KG) without interbody or posterolateral fusion with or without decompression. The cosmoMIA system is a pedicle-based dynamic system with a hinged joint between the screw head and threaded part of the screw, allowing residual movement between the rod and the screw in flexion-extension (Fig. 1). The implant allows load sharing between the spinal segment and the implant.4,6,8–10

The trial was performed at 18 centers in Germany and Austria (see Appendix). Surgeons involved were experienced in fusion and dynamic stabilization. The method of decompression (laminectomy or less-invasive techniques such as hemilaminectomy or laminotomy) was the surgeon’s choice.

Data Collection and Endpoints

Patient data were collected prior to surgery; before discharge; and at 3, 12, and 24 months after surgery. Data gathered included the Oswestry Disability Index (ODI) score, the SF-36 questionnaire Physical Component Summary (PCS) score, leg and back pain on rest and spinal loading on a visual analog scale (VAS), and the Patient Satisfaction Index (PSI). The PSI is a 4-point rating scale as follows: 1, “Surgery met my expectations”; 2, “Surgery improved my condition enough that I would go through it again for the same outcome”; 3, “Surgery helped me, though I would not go through it again for the same outcome”; and 4, “I am the same or worse compared to before the surgery.” A

<table>
<thead>
<tr>
<th>TABLE 1. Inclusion and exclusion criteria</th>
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<tbody>
<tr>
<td>Inclusion</td>
</tr>
<tr>
<td>Mono- or bisegmental symptomatic</td>
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<tr>
<td>lumbar degenerative disease w/ or</td>
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<tr>
<td>w/o canal stenosis</td>
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<tr>
<td>Indication for fusion/stabilization</td>
</tr>
<tr>
<td>1) ≥ 5 mm spondylolisthesis or segmental</td>
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<tr>
<td>instability of ≥ 3 mm or ≥ 10° on</td>
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<tr>
<td>flexion-extension imaging, or</td>
</tr>
<tr>
<td>2) predominant back pain w/ Modic</td>
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<tr>
<td>changes</td>
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<tr>
<td>Failure of conservative therapy for</td>
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<tr>
<td>&gt;3 mos</td>
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<tr>
<td>Age ≥ 18 yrs</td>
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<tr>
<td>Exclusion</td>
</tr>
<tr>
<td>Spondyloysis</td>
</tr>
<tr>
<td>Previous lumbar stabilization or fusion</td>
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<tr>
<td>Significant comorbidities w/</td>
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<tr>
<td>potential influence on surgical success</td>
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<tr>
<td>(e.g., advanced osteoporosis, rheumatoid</td>
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<tr>
<td>arthritis, mental disease)</td>
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neurological examination was performed at all time points, and information on adverse events and changes in medication was gathered. Patients were blinded to their treatment; the 12- and 24-month outcome data were assessed by an evaluator blinded for the treatment arm as well.

The primary endpoint of the study was to show between-group differences in ODI 24 months after intervention. Secondary endpoints included an overall success rate defined as 1) at least 15% improvement in ODI score from baseline to month 24, 2) maintenance or improvement of neurological status, 3) no second surgery at the treated level, and 4) no serious adverse event associated with the instrumentation at 24 months. Secondary endpoints were between-group differences at 24 months of low-back pain on the VAS, health-related quality of life measured by the PCS of the SF-36, PSI, and ODI. Adverse events were classified as serious/not serious and related/not related to the procedure or product. Adverse events were coded according to MedDRA version 19.1 (German).

Health Economic Evaluation
An economic evaluation alongside the clinical trial was conducted to evaluate costs from a payer’s perspective according to German recommendations. Costs of hospitalization, outpatient treatment, drugs, and further direct and indirect costs such as reduction of working hours, quitting work, and days off due to the lumbar disease were assessed based on a patient questionnaire examining the 3-month period prior to inclusion in the study and after treatment. The EQ-5D score was assessed at baseline and 12 and 24 months.

Statistical Analysis
Sample size calculation was performed for the primary endpoint using the two-group t-test for fold change assuming log-normal distribution, results from previous data, and nQuery Advisor version 7.0 (Statsols). It was assumed that the coefficient of variation would be approximately 0.5 within the treatment groups. Thus, a sample size of approximately 185 patients per group was required to detect an n-fold difference of at least 1.15 in the ODI with 80% power on a 2-sided level of significance of 0.05. Adding a dropout rate of 15% increased the sample size to 440 patients (220 per group).

All analyses except safety were performed on the full analysis set (FAS), which was based on the intention-to-treat (ITT) principle. It contained all randomized patients with results attributed to their treatment group who had complete preliminary examinations and started surgery. Safety analyses were performed “as treated” on the safety set, which consisted of all patients in the FAS who started the surgical procedure.

Missing baseline ODI values did not occur due to the FAS definition. The last observation carried forward (LOCF) approach was employed to analyze the primary efficacy endpoint. Additionally, complete case and Markov Chain Monte Carlo multiple imputations were applied. The results did not differ substantially from the primary analysis. No other missing data were imputed.

The 2 treatment arms were compared and tested on the FAS for superiority of the experimental over the comparator arm in terms of ODI scores 2 years after surgery.

As randomization was stratified by center and decompression, the primary endpoint analysis needed to include those variables as factors. Unfortunately, several centers had very low recruitment, which justifies the exclusion of center from the analysis. An ANCOVA including ODI baseline score, two-level factor decompression as adjustment covariates, and intervention group as the two-level factor variable was used to compare treatment groups with respect to ODI 2 years postintervention. A 2-sided evaluation of the adjusted group contrast regarding ODI level 2 years postintervention (proof of efficacy) was performed at a 0.05 significance level. Secondary endpoints were analyzed in an exploratory manner at a 2-sided 0.05 significance level. Between-group differences were tested depending on the underlying distribution using the chi-square test, Fisher’s exact test, independent-samples t-test, or the Wilcoxon rank-sum test.

Statistical analyses were performed using SAS, version 9.3 (SAS Institute Inc.) or IBM SPSS Statistics, version 21.0 (IBM Corp.).

Role of the Funding Source
The study was supported by a grant from ulrich medical GmbH & Co. KG. The funding source was not involved in
Results

Trial Participants

From August 2011 to October 2015, 293 patients were randomized. As the study stopped early due to slow recruitment, a post hoc power analysis revealed that the actual power of the study using the original assumptions was 67.6%. Of 293 patients, 24 were excluded from the FAS, as 19 had missing baseline data and 5 did not undergo surgery. Finally, 269 patients (137 in the fusion group and 132 in the dynamic stabilization group) were available for an ITT analysis (Fig. 2). Four of the patients assigned to dynamic stabilization underwent fusion. Those were included “as randomized” in the ITT analysis and “as treated” in the safety analysis. Baseline characteristics of the ITT population are given in Table 2 without significant differences between groups. The indications for stabilization were not different between groups, as well as the baseline pain and health-related quality of life.

For the final follow-up, 101 (73.7%) patients were available in the fusion group and 96 (72.7%) in the dynamic stabilization group (Fig. 2). A total of 190 patients had ODI scores at final follow-up (97 in the fusion group and 93 in the dynamic stabilization group), which means that 79 scores had to be imputed for the primary endpoint analysis.

Surgical Parameters

Levels treated and surgical parameters are summarized in Table 3. Levels ranged from L1–2 to L5–S1 with a maximum at L4–5 for both groups. Ninety-two (67%)
TABLE 2. Patient characteristics at baseline in the ITT population

<table>
<thead>
<tr>
<th>Parameter</th>
<th>FU (n = 137)</th>
<th>DY (n = 132)</th>
<th>p Value</th>
</tr>
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<tbody>
<tr>
<td>Female sex</td>
<td>70 (51)</td>
<td>76 (58)</td>
<td>0.255*</td>
</tr>
<tr>
<td>Age, yrs</td>
<td>64 ± 11</td>
<td>64 ± 12</td>
<td>0.842†</td>
</tr>
<tr>
<td>BMI</td>
<td>28 ± 5</td>
<td>27 ± 4</td>
<td>0.186†</td>
</tr>
<tr>
<td>Indication for stabilization</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spondylolisthesis</td>
<td>53 (39)</td>
<td>60 (45)</td>
<td>0.261*</td>
</tr>
<tr>
<td>Instability</td>
<td>28 (20)</td>
<td>20 (15)</td>
<td>0.258*</td>
</tr>
<tr>
<td>Predominant back pain</td>
<td>68 (50)</td>
<td>63 (48)</td>
<td>0.754*</td>
</tr>
<tr>
<td>Other</td>
<td>17 (12)</td>
<td>14 (11)</td>
<td>0.643*</td>
</tr>
</tbody>
</table>

Patient-reported outcome data

| VAS back (rest)         | 4.8 ± 2.9    | 4.6 ± 2.9    | 0.754†  |
| VAS leg (rest)          | 4.2 ± 3.1    | 3.8 ± 2.8    | 0.351†  |
| VAS back (load)         | 6.5 ± 2.5    | 6.1 ± 2.8    | 0.312†  |
| VAS leg (load)          | 6.1 ± 3.0    | 5.6 ± 3.1    | 0.207†  |
| ODI                     | 44.7 ± 17.6  | 43.4 ± 17.4  | 0.534†  |
| SF-36 MCS               | 45.0 ± 14.6  | 43.8 ± 13.5  | 0.554†  |
| SF-36 PCS               | 28.2 ± 6.8   | 28.3 ± 6.7   | 0.891†  |

FU = fusion; DY = dynamic stabilization; MCS = Mental Component Summary. Values are presented as the number of patients (%) or mean ± SD unless stated otherwise.
* Chi-square test.
† Independent-samples t-test.

patients were treated monosegmentally and 45 (33%) bisegmentally in the fusion group, versus 96 (73%) and 36 (27%), respectively, in the dynamic stabilization group. Decompression in addition to fusion or dynamic stabilization was performed in 130 (95%) fusion patients and 124 (94%) dynamic stabilization patients. In the fusion group, 58% of decompressions were less-invasive fenestrations, while 42% were laminectomies versus 73% fenestrations and 27% laminectomies in the dynamic stabilization group. The mean duration of surgery was 211 ± 89 minutes for fusion and 184 ± 66 minutes for dynamic stabilization. The mean duration of surgery was 211 ± 89 minutes for fusion and 184 ± 66 minutes for dynamic stabilization. The mean PSI scores at final follow-up were 17.0 ± 2.4 (p = 0.003) in the fusion group and from 17.0 ± 2.4 to 17.0 ± 2.4 in the fusion group. Likewise, back pain and pain intensity improved within groups but did not differ between groups. The SF-36 PCS scores for the fusion and dynamic stabilization groups improved from 28.2 ± 6.8 to 28.3 ± 6.7, respectively, at baseline to 24 months and were not statistically different. The mean PSI scores at final follow-up were 17.0 ± 1.0 and 1.9 ± 1.0 for the fusion and dynamic stabilization groups, respectively. At the 24-month follow-up, 39 patients per group reported ongoing or worsened pain.

Endpoints (ITT analysis)

Regarding the primary endpoint (ODI score at 24 months after intervention), there was no significant difference between the 2 treatment groups (ANCOVA, p = 0.128). The mean difference in ODI at 24 months was 0.890, with changes of 17 ± 20 and 12 ± 21 for fusion and dynamic stabilization, respectively.

The overall success rates were 46% (63/137) in the fusion group and 39% (51/132) in the dynamic stabilization group, with no statistical significance (p = 0.327) (Table 4).

The mean intensity of low-back pain at rest improved from 4.8 ± 2.9 at baseline to 2.0 ± 2.2 at 24 months in the fusion group and from 4.6 ± 2.9 to 2.2 ± 2.0 in the dynamic stabilization group. Likewise, back pain on loading improved for both groups at all points, as well as leg pain at rest or loading. Pain intensity improved within groups but did not differ between groups. The SF-36 PCS scores for the fusion and dynamic stabilization groups improved from 28.2 ± 6.8 and 28.3 ± 6.7, respectively, at baseline to 24 months and were not statistically different. The mean PSI scores at final follow-up were 17.0 ± 1.0 and 1.9 ± 1.0 for the fusion and dynamic stabilization groups, respectively. At the 24-month follow-up, 39 patients per group reported ongoing or worsened pain.

Secondary Procedures and Adverse Events

Until final follow-up, 141 additional procedures (mostly minor) were necessary; 121 additional infiltration therapies of facet joints, iliosacral joints, and the epidural space were performed (65 cases in the fusion group and 56 cases in the dynamic stabilization group). Twenty reoperations (9 in fusion and 11 in dynamic stabilization patients) were performed for decompressions (3 fusion and 6 dynamic stabilization patients) and screw-related problems (4 fusion and 3 dynamic stabilization patients), complete replacement of instrumentation (1 fusion and 3 dynamic stabilization patients), or other reasons (5 fusion and 2 dynamic stabilization patients). A total of 106 spine-associated complications occurred (Table 5). Fifty-three medical complications were reported for fusion (n = 27) and dynamic stabilization (n = 26). The overall frequency as well as the frequencies of procedure- or product-related and unrelated adverse events were not different between groups. Likewise, outcomes of the adverse events and serious adverse events were not different.
Health Economic Evaluation

Within 3 months prior to surgery, the mean number of physician consultations per patient in the fusion group was 2.7 (range 0–12), and that for the dynamic stabilization group was 3.1 (range 0–13). Some patients specified that they had lost days of work (15.0% of fusion and 15.8% of dynamic stabilization patients) due to lumbar degenerative disease, with a mean of 33.2 days (33.8 days and 32.2 days...
pedicle-based stabilization of 1 or 2 segments. In addition to the lack of difference in functional outcomes, the number of procedure-related or implant-related adverse events and secondary procedures was not different. Secondary endpoints such as overall success and patient satisfaction did not differ between treatment groups. However, there were differences in the duration of surgery and intraoperative blood loss, with shorter duration and less blood loss for dynamic stabilization, resulting in lower hospital treatment costs.

The rate of lumbar fusion surgeries for degenerative disease has increased rapidly during recent years. Various surgical techniques of instrumented and noninstrumented fusion are used in these surgeries. In parallel with the increasing rate of fusion surgeries, indications in degenerative disease have been assessed in recent studies identifying subgroups of degenerative instabilities necessitating fusion for adequate functional outcome. While degenerative spondylolisthesis per se is no longer accepted as an indication for fusion, various for the present trial, accepted inclusion criteria for lumbar fusion were ≥ 5 mm spondylolisthesis, ≥ 3 mm or ≥ 10° mobile spondylolisthesis, or predominant back pain with Modic changes. For this subgroup of patients with degenerative instabilities, fusion was compared with dynamic pedicle-based stabilization.

The ideal technique for fusion remains unclear, and many variations are available. While motion reduction and fusion rates with the use of the older noninstrumented techniques are potentially low, more modern instrumented pedicle-based stabilization together with interbody fusion by different approaches has become an established technique. Various technical approaches to interbody fusion have been compared in many studies. While the complication rates and types depend on the approach, functional patient outcomes and fusion rate do not depend on whether interbody fusion is anterior, posterior, transfemoral, or lateral. However, all approaches necessitate additional soft-tissue manipulation with removal of disc material from the interbody space and implantation of fusion material. Side effects of interbody fusion relate to the surgical invasiveness based on the approach to the anterior column and of fusion itself, with the potentially associated increased adjacent-segment strain that can lead to radiological or symptomatic degeneration.

In contrast, pedicle-based dynamic stabilization is...
based on the reduction of pathological painful motion and preservation of residual nonpathological painless motion.\(^6\) Theoretical advantages are reduced surgical invasiveness and adjacent-level strain.\(^{26,27}\) Different types of pedicle-based stabilization devices have been assessed in uncontrolled and controlled lower-quality trials with contradictory results and a high rate of screw failure for some of the assessed devices.\(^{28–31}\) The present trial is the first high-quality, controlled, blinded study revealing a similar clinical efficacy of dynamic pedicle-based stabilization in comparison with fusion with reduced surgical invasiveness, with the same number of procedure- and implant-related complications. The rate of symptomatic adjacent-segment degeneration was not different between groups.

In a biomechanical analysis, the dynamic stabilization of the present study reduced motion of an intact segment by 53% for lateral bending, 21% for axial rotation, 68% for flexion, and 40% for extension.\(^8\) So far, the in vivo long-term effect of this motion reduction and preservation of residual motion remains ambiguous. However, 2 uncontrolled studies revealed that motion reduction leads to a functional outcome comparable to that of fusion with a mean ODI score improvement of 26.4–30, a VAS pain score improvement of 4.4–4.8, and a SF-36 PCS score improvement of 5 points, associated with implant-related reoperation rates of 2.8% and 2.9% after mean follow-ups of 15 and 24 months, respectively.\(^4,6\) Whether the residual motion leads to any change in adjacent-segment strain, is just sufficient to avoid pedicle screw loosening, or is lost by slow delayed fusion remains undetermined.

Screw loosening or implant breakage is a common concern in dynamic pedicle-based stabilization and has been reported for the Dynesys system in several series. A previous retrospective study reported screw loosening in 19.7% of 71 patients as assessed by CT scans obtained 18–24 months after surgery.\(^32\) The same group evaluated a larger cohort of patients at an average follow-up of 51.1 months and detected screw loosening in 20.4% of patients.\(^33\) These data demonstrate that radiographic screw loosening seems to occur within 2 years after surgery, mostly without a relevant increase during later follow-up. Furthermore, radiographic screw loosening was not associated with clinical decline.\(^32,33\) The rate of radiographic screw loosening in the present study remains largely unclear; as no follow-up CT scans were obtained within the protocol, and radiographs allow a limited evaluation of screw loosening. However, the hydroxyapatite coating of the dynamic system used in the present study is intended to avoid screw loosening, and the incidence of symptomatic implant-related complications was not increased in dynamic stabilization in comparison with fusion, thereby showing no increased risk of symptomatic implant failure. In addition to screw loosening, previous retrospective studies on lumbar dynamic stabilization with the Dynesys device have revealed that the rationale of maintaining motion was not achieved in some cases, where dynamic stabilization induced slow fusion. When evaluating postoperative segmental motion in previous studies, several cases showed segmental motion below 3\(^\circ\) on flexion-extension radiographs.\(^34,35\) In another study, CT scans obtained 18–24 months postoperatively demonstrated an unintended facet joint arthrodesis in more than 50% of cases with Dynesys stabilization.\(^36,37\) Whether slow fusion was associated with dynamic stabilization in the present study remains unclear, as fusion in the dynamic stabilization and fusion groups was not systematically assessed by CT scans as recommended for the evaluation of fusion.\(^38\) However, irrespective of a potential slow fusion in dynamic stabilization, the benefit of reduced surgical invasiveness while achieving the same clinical results in comparison with fusion remains.

To elucidate the aspects of further symptomatic screw loosening, slow fusion, and adjacent-segment degeneration in the present series of patients, further long-term observation and a thorough analysis of further follow-up imaging by CT are necessary. Regarding adjacent-segment disease, the present follow-up of 2 years was too short to establish differences in symptomatic or asymptomatic adjacent-segment degeneration between groups.

However, a benefit of the less-invasive dynamic technique was proven in terms of reduced operating room time and intraoperative blood loss, with no functional outcome differences in comparison with fusion.

The cohort assessed in the present study showed marginal differences in baseline values without any significant differences. After treatment, minimal clinically important differences (MCIDs) for lumbar fusion are 1.2 for back pain, 1.6 for leg pain, 12.8 for ODI, and 4.9 for SF-36 PCS scores.\(^39\) These values were reached or exceeded for all time points except the final 2-year ODI of the dynamic stabilization arm. With a value of 12, the MCID for ODI was marginally not reached, while the MCID was exceeded for VAS back and leg pain and SF-36 PCS for this time point. Likewise, the proportion of patients reaching an ODI improvement of \(\geq 15\%\) at 2 years was slightly lower in the dynamic stabilization group, as well as the overall success rate. However, these differences did not reach significance, and overall ODI scores at different time points showed no differences. Therefore, these marginal differences between groups might be attributable to the sample size decreasing due to patient dropout.

While outcome assessment of the primary endpoint was performed by a blinded assessor and patients were blinded to the treatment arm to reduce bias, blinding of the surgeons was not possible. Therefore, surgeons were not involved in the final evaluation to reduce bias. Despite structured study monitoring, the patient dropout rate during follow-up was higher than estimated when calculating the initial sample size, weakening the results of the study. However, dropout rates showed the same proportion in both arms, and baseline values of lost patients as well as ODI scores were not different between groups before dropout and inclusion criteria. The analysis of the data using the LOCF approach compensates for these patients but does carry some risk of bias. To reduce this risk, LOCF was compared with multiple imputations, which did not reveal different results.

While the present study shows equivalent functional outcomes of fusion and dynamic stabilization with reduced surgical complexity and invasiveness as well as reduced costs in the dynamic group, these results cannot be generalized without limitations to other pedicle-based dynamic implants, since methods of dynamization are variable be-
tween devices. However, dynamic pedicle-based systems with similar mechanisms could lead to comparable results to those found in the present study.

The study follow-up duration of 2 years does not exclude any changes in functional outcome between groups beyond this time point. Further advantages and disadvantages of fusion or dynamic stabilization might occur during later follow-up as adjacent-segment problems or late implant failure. To elucidate for these potential problems, further long-term follow-up is necessary.

Conclusions

The present study shows that dynamic pedicle-based stabilization for lumbar degenerative mono- or bisegmental instability can have functional results similar to the standard of transforaminal lumbar fusion. While procedure- and product-related complications as well as overall complications were not different between groups, surgical invasiveness and associated costs were reduced in the dynamic stabilization group. Therefore, dynamic pedicle-based stabilization is a beneficial alternative to fusion for selected cases.

Appendix

DYNOTFUSE Study Group

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Disclosures

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Author Contributions

Conception and design: Ringel, Meyer, Thomé, Vajkoczy, Dodel. Acquisition of data: Ringel, Meyer, Thomé, Vajkoczy. Analysis and interpretation of data: Ringel, Meyer, Kehl, Dodel. Drafting the article: Ringel, Kehl, Dodel. Critically revising the article: Ringel, Thomé, Vajkoczy, Dodel. Dissemination of results: Ringel, Meyer, Thomé, Vajkoczy. Reviewed submitted version of the manuscript: Ringel, Meyer, Thomé, Vajkoczy. Reviewed submitted version of the manuscript: Ringel, Meyer, Thomé, Vajkoczy, Dodel. Reviewed submitted version of the manuscript: Ringel, Mey, Thomé, Vajkoczy, Dodel. Approved the final version of the manuscript on behalf of all authors: Ringel. Statistical analysis: Ringel, Kehl. Study supervision: Ringel, Meyer.

Supplemental Information

Previous Presentations

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