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CLINICAL ARTICLE

# Pedicle screw-based dynamic stabilization of the thoracolumbar spine with the Cosmic®-system: a prospective observation

**Michael Stoffel · Michael Behr · Andreas Reinke · Carsten Stüer · Florian Ringel · Bernhard Meyer**

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**Abstract**
*Object* The objective of the study was to generate prospective data to assess the clinical results after dynamic stabilization with the Cosmic® system (Ulrich Medical).
*Patients and methods* Between April 2006 and December 2007, 103 consecutive patients were treated with Cosmic® for painful degenerative segmental instability ± spinal stenosis. The preoperative workup included radiological (MRI and myelography/CT) and clinical parameters (general/neurological examination, visual analogue scale (VAS), Oswestry disability index (ODI), SF-36, Karnofsky (KPS)). At pre-defined intervals (at discharge, 6 weeks, 3 months, 6 months, 12 months, and yearly) the patients were reevaluated (X-ray/flexion/extension, neurological status, VAS, ODI, SF-36, KPS, and patient satisfaction). Data were collected in a prospective observational design.
*Results* Data collection was completed in 100 of 103 operated patients (mean follow-up, 15±0.6 months). Dynamic stabilization was performed as first-tier surgery in 43 cases and as second-tier therapy in 60 cases. Additional decompression was performed in 83 cases. Dynamic stabilization led to significant reduction of back pain-related disability (ODI pre-op, 51±1%; post-op, 21±1%) and improvement of pain (VAS pre-op, 65±1; post-op, 21±2), mental/physical health (norm-based SF-36: mental pre-op, 44; post-op, 48; physical pre-op, 41; post-op, 46), and mobility (KPS pre-op, 70±1; post-op, 82±31). Early reoperation was necessary in 12 patients ($n$=3 symptomatic misplaced screws, $n$=8 CSF pseudocele, rebleeding, or impaired wound healing, $n$=1 misjudged instability/stenosis in adjacent segment). Reoperations within the follow-up period were necessary in another 10 patients due to secondary screw loosening ($n$=2), persistent stenosis/disk protrusion in an instrumented segment ($n$=3), symptomatic degeneration of an adjacent segment ($n$=6), or osteoporotic fracture of an adjacent vertebra ($n$=1), respectively. Patient satisfaction rate was 91%.
*Conclusions* Dynamic stabilization with Cosmic® achieved significant improvement of pain, related disability, mental/physical health, and mobility, respectively, and a high rate of satisfied patients. A reoperation rate of 10% during follow-up seems relatively high at first glance. Comparable data, however, are scarce, and a prospective randomized trial (spondylodesis vs. dynamic stabilization) is warranted based on these results.

**Keywords** Disk degeneration · Dynamic stabilization · Lumbar spine · Non-fusion · Thoracic spine · Treatment

## Introduction

Pain evolving from the degenerated motion segment is linked to its pathologic mobility. Suppression of the latter should induce pain relief. Hence, surgically induced fusion became the golden standard for disk degeneration, segmental instability, and spondylolisthesis. A variety of surgical fusion techniques have been performed during the last century. As yet, the clinical results of these techniques are not better than acceptable (mean Δ ODI, 18.3), and all techniques are associated with considerable complications [2, 4, 8, 9, 11, 18, 21, 28]. No particular technique has been demonstrated to achieve superior clinical results; however,

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incidence and severity of complications seem to increase with increased technicality of the respective surgical technique [4, 8, 22, 26]. While radiographically confirmed fusion rates have exceeded 95%, this does not translate into improvement of successful clinical outcomes, which are achieved in approx. 70% [3, 22, 26]. This fact seems to indicate that solid bony fusion is not the parameter that determines the clinical success. Above that, concerns have been raised related to adjacent-level disease found in long-term patient follow-up after spondylodesis [5, 6, 10, 17]. From the clinical standpoint, the sacrifice of a degenerated disk might not be necessary and desirable. Several investigators have even questioned the efficacy of spinal fusion in the treatment of low back pain [11].

Dynamic stabilization aims at providing stability to eliminate the pain by permitting restricted movement across the stabilized motion segment. The dynamic stabilization systems seem to work either by restricting movement to a zone or range at which normal or near-normal loading can occur or by preventing the spine from adopting a position in which abnormal loading occurs [20]. Cosmic® is a pedicle screw-based stable nonrigid implant system that stabilizes the spine in the case of painful degenerative disease. The load sharing between implant system and anterior vertebral column is provided by a hinged joint between the head of the pedicle screw and the threaded part. Laboratory tests have proven that Cosmic® allows the same rotation stability as a healthy motion segment, while motion in flexion–extension shows a 65% reduction, and motion in lateral bending shows a 90% reduction compared to the intact spine [25]. The pedicle screws are coated with Bonit®—a second-generation bioactive calcium phosphate—to insure optimal bone healing [23]. As shown by von Strempel et al., Cosmic® surgery is faster and less afflicted with complications than spondylodesis [29].

The objective of the present study was to follow all procedures performed with the Cosmic® posterior dynamic system in patients with degenerative thoracolumbar spine disease at our service consecutively on a prospective basis, focusing on clinical outcome, procedure-related complications, stability of the construct, and reoperations.

## Materials and methods

### Patient characteristics

One hundred three patients (m=38, f=65, median age 65 years; range, 30–88) with painful degenerative lumbar or lower thoracic segmental instability with/without spinal stenosis have been treated with the posterior dynamic system Cosmic® between April 2006 and December 2007. Instability was defined as pathological micro- or macro-motion (i.e., detectable on flexion/extension radiographs or not) held responsible—at least in part—for the respective back pain and/or pseudoradicular leg pain. This was assumed, if degenerative pseudospondylolisthesis, osteochondrosis (disk space narrowing/endplate osteosclerosis/osteophytes), or opening of the disk space in flexion was detected on the radiographs.

The patients underwent physical examination (including Karnofsky (KPS) assessment), reported their subjective pain according to the visual analogue scale (VAS), and responded to the Oswestry disability and the SF-36 questionnaire at pre-defined time intervals (i.e., preoperatively, at discharge, at 6 weeks, 3 months, 6 months, 12 months, and yearly thereafter). Preoperatively, a MRI and—in most cases—a myelogram, including flexion/extension films and a post-myelo-CT, were obtained. In cases where the origin and/or the segmental height of back pain were unclear, facet joint injections served as additional diagnostic tool. Informed consent was obtained in all cases. Prior to discharge, a routine postoperative CT scan served as quality control to assess the position of the implanted material and the decompression if performed. Postoperatively and at each follow-up visit, radiographs of the thoracolumbar region, including flexion/extension films, were performed. Data were collected in a prospective observational design.

### Operative procedure

The posterior instrumentation was performed under general anesthesia. The patients were positioned prone on a gel-filled mattress that supported the thorax and pelvis. A single dose of prophylactic antibiosis (i.v. 1.5 g cefuroxim) was administered 30 min before skin incision. In cases where the spinal canal had to be opened for stenosis decompression or previous implants had to be removed, respectively, a midline incision was followed by subperiostal preparation of the paraspinal muscles. In cases where solely dynamic stabilization was performed, two paramedian skin incisions and a transmuscular approach according to Wiltse were made [31]. The pedicle screws were implanted under fluoroscopic and landmark control. Before final connection with the rod system, stenosis decompression —mostly extended interlaminar fenestration including undercutting to the contralateral side—was performed if indicated using a high-speed drill and Kerrison punches of different sizes. Finally, two vacuum wound drainages were left subfascially, and the wound was closed layer by layer.

### Cosmic® dynamic system

The Cosmic® posterior dynamic system (Ulrich Medical, Ulm, Germany) is a pedicle screw-based stable nonrigid

implant. Stability is assured by the 6.25-mm threaded rod, and nonrigidity is assured by the hinged screw head (Fig. 1). The screw features a hinged joint between head and threaded part, which causes the load to be shared between implant system and anterior vertebral column. Laboratory tests in destabilized spine segments have shown that Cosmic® allows the same rotation stability as a healthy motion segment, while motion in flexion–extension shows a 65% reduction, and motion in lateral bending shows a 90% reduction compared to intact spine values [25]. The threaded part of the screw is coated with Bonit® —a second-generation bioactive calcium phosphate—to insure optimal bone healing. Bonit® is well known in oral surgery for dental implants [15]. Calcium phosphate coating on Schanz screws has been shown to significantly improve fixation compared to uncoated screws [23].

### Data analysis

To test the influence of the operative treatment on the study parameters, the data acquired before operation and at the latest follow-up visit were analyzed by the Wilcoxon signed rank test for dependent samples. To test for differences between the groups (olisthesis and no olisthesis), the Mann–Whitney rank sum test was used. Data are presented as mean ± standard error of the mean (mean ± SEM). A probability of $p<0.05$ was required to reject the null hypothesis and to indicate a statistically significant difference.

## Results

Data collection was completed in 100 of 103 operated patients (mean follow-up, 15±0.6 months). Three patients were lost for follow-up. Dynamic stabilization was performed as first-tier surgery in 43 cases and as second-tier therapy in 60 cases (i.e., at least one preceding operation in the respective region of the spine). In 51 patients, degenerative pseudospondylolisthesis was present on the radiographs; in 52 patients, osteochondrosis or macroinstability without olisthesis led to the assumption of clinically apparent instability. Five hundred fourteen pedicle screws were implanted into 270 vertebrae (Th11–S1) to dynamically stabilize one ($n$=47), two ($n$=47), or three segments ($n$=9), respectively (Figs. 2 and 3). Additional decompression was performed in 83 cases. Early reoperation within the first days after primary surgery was necessary in 12 patients. The indications for reintervention were revision of symptomatic misplaced screws ($n$=3), revision of CSF pseudoceles, hematomas, or impaired wound healing, respectively ($n$=8), and a misjudged instability/stenosis in an adjacent motion segment ($n$=1). No postoperative neurological deterioration (transient/permanent) had occurred.

Dynamic stabilization led to significant improvement of pain (VAS pre-op, 65±1; post-op, 21±2, $p<0.001$) and performance (KPS pre-op, 70±1; post-op, 82±1, $p<0.001$) and a significant reduction of back pain related disability (ODI pre-op, 51±1%; post-op, 21±1%, $p<0.001$) (Fig. 4a–c). This means that the according to the ODI preoperatively, on average, severely disabled patients (ODI 40–60%) were only moderately disabled in the last follow-up (ODI 20–40%). The analysis of these outcome parameters separated for the patient group with olisthesis and the patient group without olisthesis brings the following results: The patients *with olisthesis* experienced an improvement of pain from 67±2 pre-op to 21±3 post-op (VAS), an improvement of performance from 70±1 pre-op to 81±1 post-op (KPS), and a reduction of disability from 50±1 pre-op to 23±2 post-op (ODI). The patients *without olisthesis* improved from 62±2 pre-op to 21±2 post-op on the VAS, from 70±1 to 83±1 on the KPS, and from 52±1 to 20±2 on the ODI. There were no statistically significant differences in either parameter between these two patient groups.

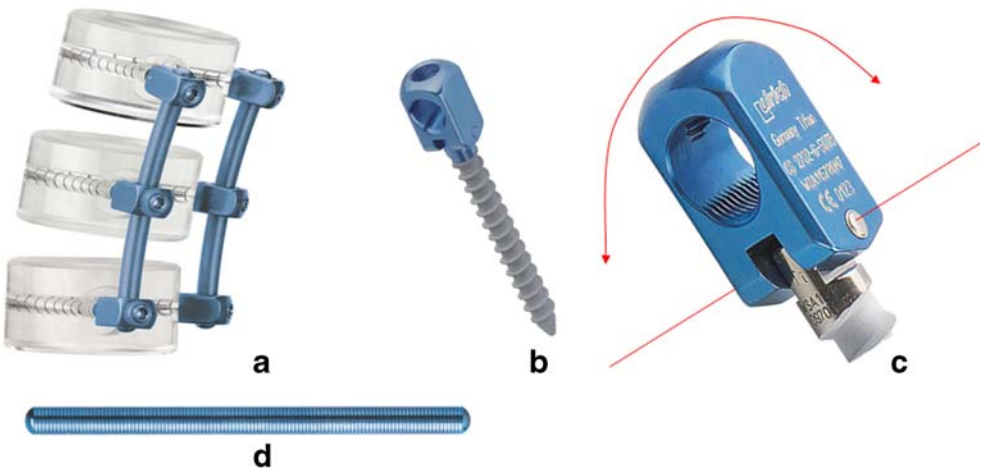


**Fig. 1** The Cosmic® posterior dynamic system (Neon; Ulrich GmbH, Ulm, Germany). **a** The complete construct mounted on a Plexiglas spine model. **b** The surface of the pedicle screw is coated with the resorbable calcium phosphate Bonit®. **c** The screw hinge only allows axial load distribution and reduces rotation and translation. **d** The threaded rod supports the screw-rod connection

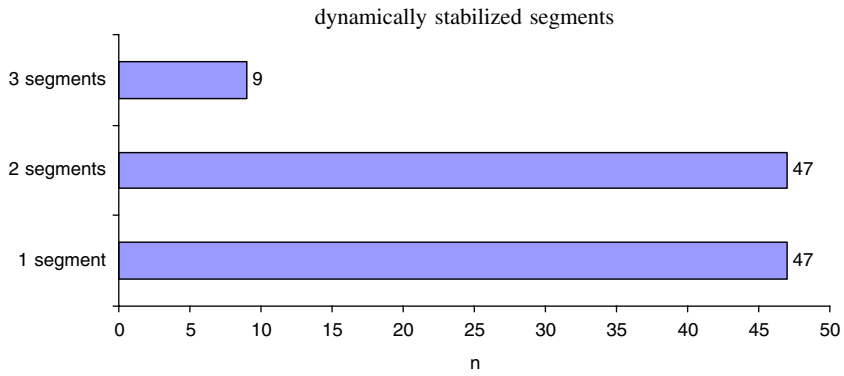


**Fig. 2** Number of patients dynamically stabilized in one, two, and three segments, respectively

The results of the SF-36 questionnaire are given in a dichotomized fashion, summarized in a mental and in a physical health component (Fig. 4d). Both components reflect a statistically significant improvement of the subjectively felt health between the preoperative status and the status at last follow-up (norm-based SF-36: mental pre-op, 44; post-op, 48; physical pre-op, 41; post-op, 46, $p<0.01$).

Reoperations within the follow-up period were necessary in 10 patients due to symptomatic advanced degeneration of an adjacent segment ($n=6$), persistent stenosis/disk protrusion of an instrumented segment ($n=3$), secondary screw loosening ($n=2$), or osteoporotic fracture of an adjacent vertebra ($n=1$), respectively (Table 1). Thereby, in one patient, the combination of screw loosening and preexisting stenosis (Table 1, patient 3) and in one other patient the combination of screw loosening and advanced preexisting adjacent-level degeneration (Table 1, patient 8) led to the revision surgery. In two patients (Table 1, patients 2 and 7), a persistent recess stenosis or intraforaminal disk herniation, respectively, that were not eliminated in the Cosmic® operation and caused persisting sciatica, led to the revision surgery after 3 months. Accordingly, eight patients had to be reoperated within the follow-up period due to secondarily occurring complaints and new findings on the radiographs. Of these eight patients, seven had a degenerative pseudolisthesis, and only one had no olisthesis prior to the Cosmic® surgery. Accordingly, seven out of 51 patients (14%) with olisthesis developed secondarily occurring complaints and new findings on the radiographs that led to a reoperation, whereas only one out of 52 patients (2%) without olisthesis did. Analysis according to dynamically stabilized motion segments brings the following results: one out of 47 patients (2%) with a monosegmental dynamic stabilization, five out of 47 patients (11%) with bisegmental Cosmic®, and two out of nine patients (22%) with trisegmental Cosmic® stabilization had to be reoperated for secondarily occurring complaints and new findings on the radiographs (Table 1, Fig. 2).

The time interval between the first implantation of Cosmic® and the subsequent operation was 3–17 months (mean ± SEM, 8±1.5). Overall patient satisfaction rate—as asked at last follow-up in a dichotomized fashion (yes/no)—was 91%. Figure 5 illustrates a case of multisegmental lumbar degeneration that needed reoperation within the follow-up period (patient 1 in Table 1).

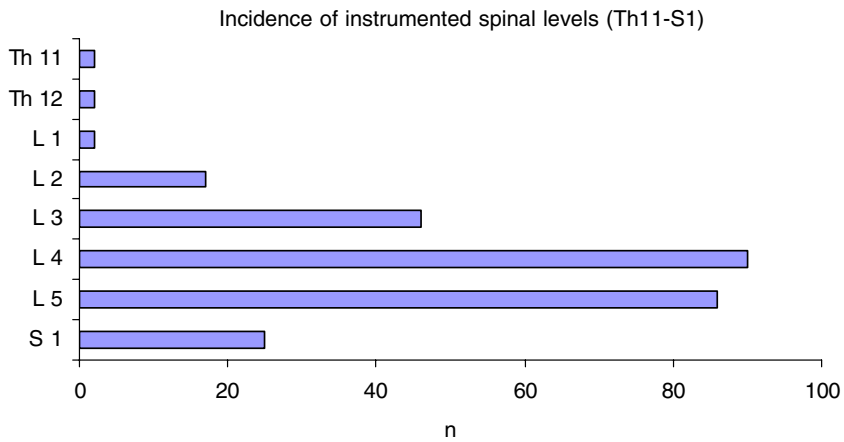


**Fig. 3** Incidence of instrumented spinal levels (Th11–S1)

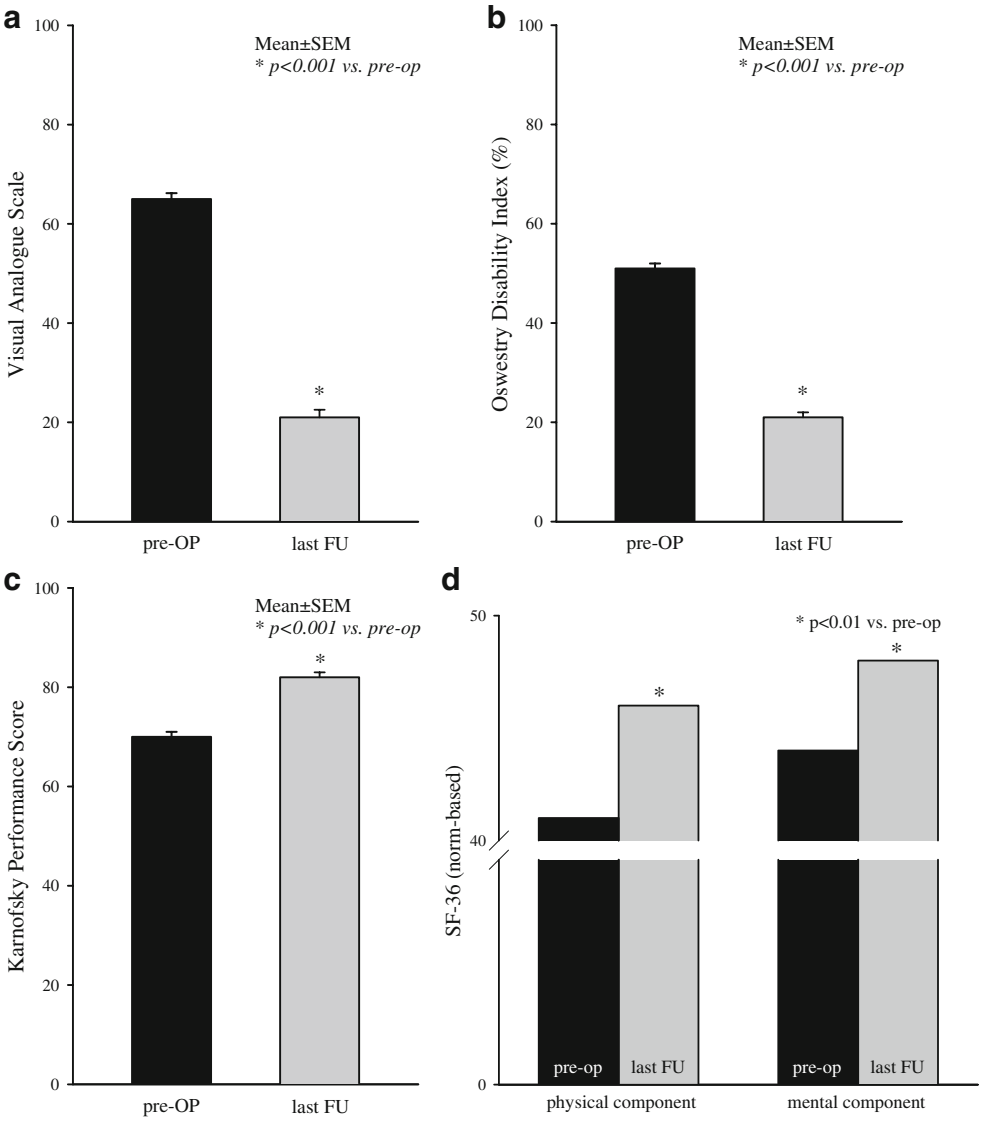


**Fig. 4** **a–c** Patients' subjective pain specification (visual analogue score), back pain-related disability (Oswestry disability index), and mobility (Karnofsky performance score). **d** Dichotomized results of the SF-36 questionnaire depicted as mental and physical health components preoperatively and at last follow-up

## Discussion

This study summarizes the results of a group of 103 patients consecutively treated by dynamic stabilization with the Cosmic® posterior dynamic system for painful degenerative segmental instability. The dynamic stabilization was the main therapeutic procedure in 20 cases, whereas additional decompression of the spinal canal was performed in 83 cases—i.e., the vast majority. This treatment was the second-tier therapy after at least one preceding operation in this region of the spine in 60%. Thereby, the general ability of this system to significantly reduce back pain and its related disability (ΔVAS, 44; ΔODI, 30) as well as to improve mental/physical health and mobility (ΔSF-36 norm-based: mental 4, physical 5, ΔKPS, 12), respectively, could be proven. The clinical outcome in respect to these parameters is independent of the presence of olisthesis.

The clinical effect of this procedure was durable in 90% of the patients during medium-term follow-up, and a high patient satisfaction rate was achieved (91%). Neither new neurological deficits nor implant breakage occurred. Early reoperations within the first days were necessary in 12 patients (three misplaced screws, eight CSF leaks/hematomas/wound problems, one misjudged adjacent segment stenosis/instability). Reoperations within the follow-up period were necessary in 10% of patients due to newly developed complaints after an interval of 3–17 months. In six of these 10 patients, symptomatic degeneration of an adjacent segment resulting in new soft-tissue space occupation occurred, whereas in two patients, a persistent stenosis/disk protrusion had to be treated secondarily. In two further patients, screw loosening or an osteoporotic fracture of the cranial instrumented vertebra occurred resulting all together in eight patients who needed reoperations due to secondarily occurring complaints and new findings on the radiographs. Among

**Table 1** Summary of patient characteristics, respective operations, and pathology leading to reoperation within the follow-up period

| No. | Age | Sex | Olisthesis | Previous operations | 1st operation | Interval to 2nd operation (months) | Reason for second operation | 2nd operation | Reason for 2nd op. |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 67 | f | 1 | 0 | Cosmic L3–5, lami L4 | 6 | Increased disk protrusion L2/3 | Cosmic elongation to L2, le h-lami L2, sq/nc L2/3 le | ■ |
| 2 | 65 | m | 1 | 1 | Cosmic L4/5, ILF L4/5 ri | 3 | Persistent intraforaminal sequester L4/5 ri | ILF L4/5 ri, sq/nc | ♦ |
| 3 | 66 | f | 1 | 1 | Cosmic L3–5, ILF L3/4 ri/le | 17 | Screw loosening L3, 5, stenosis L4/5 ri now symptomatic | Screw revision, ILF L4/5 ri | ▲, ♦ |
| 4 | 67 | f | 1 | 1 | Cosmic L4/5, | 11 | Preexisting stenosis L3/4, now symptomatic | Cosmic elongation to L3, ILF L3/4 ri | ■ |
| 5 | 59 | f | 1 | 1 | Cosmic L4–S1 | 5 | New disk herniation L3/4 ri | ILF L3/4 ri, sq/nc | ■ |
| 6 | 63 | m | 1 | 0 | Cosmic L3–5, h-lami L4 le | 12 | New disk herniation L5/S1 le | ILF L5/S1 le, sq/nc | ■ |
| 7 | 69 | f | 0 | 0 | Cosmic L4–S1, lami L4 | 3 | Persisting L5 sciatica, persistent recess stenosis L4/5 le | ILF L4/5 le | ♦ |
| 8 | 62 | m | 1 | 1 | Cosmic L2–4, sq/ncL2/3 le, ILF L3/4 ri | 8 | Screw loosening L2, enlargement of preexisting disk hern. L4/5 ri | Cosmic elongation to L5, screw revision L2, h-lami L4 ri, sq/nc | ▲, ■ |
| 9 | 69 | f | 0 | 1 | Cosmic L2–5, h-lami L3,4, sq | 10 | Preexisting olisthesis, disk herniation L5/S1 ri | ILF L5/S1 ri, sq/nc | ■ |
| 10 | 66 | m | 1 | 0 | Cosmic L2–5, ILFs L2/3, 3/4, 4/5 ri | 4 | Osteoporotic fracture L2 | COSMIC explantation (patient's wish) | ● |

*lami* laminectomy, *h-lami* hemilaminectomy, *ILF* interlaminar fenestration, *Sq* sequesterectomy, *nc* nucleotomy, *ri* right, *le* left, (■) adjacent-level degeneration, (●) osteoporotic fracture, (▲) screw loosening, (♦) persistent stenosis/disk protrusion in operated level

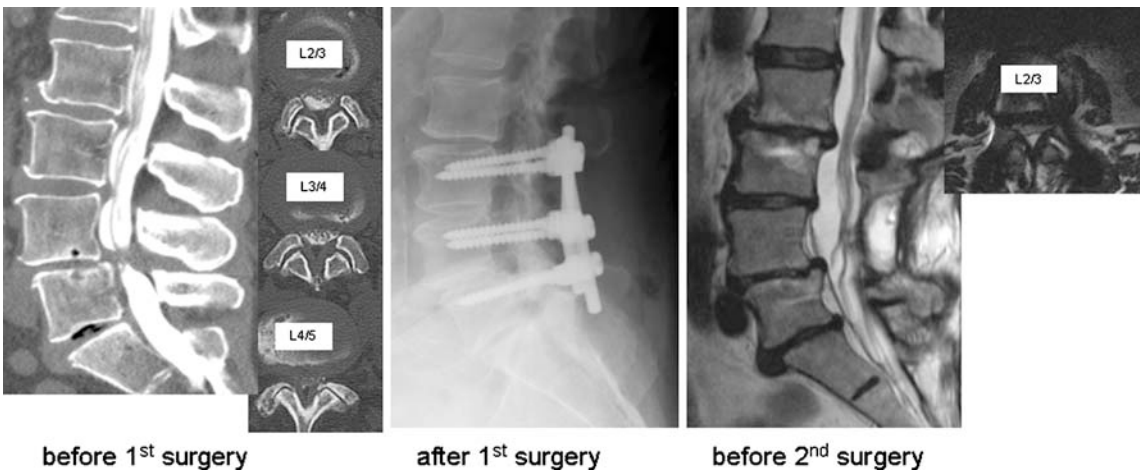


**Fig. 5** *Case illustration 1*. Preoperative status: 67-year-old woman with a 10-year history of activity related low back pain and bilateral sciatica and a spinal claudication. The complaints increased over the years and were refractory to conservative measures. The patient is significantly restricted in her activities of daily life and walking distance. No neurologic deficit. The CT myelogram reveals a L4/5 pseudospondylolisthesis Meyerding I and a severe stenosis and a relative stenosis in L3/4. Furthermore, L2/3 and L5/S1 show a decreased disk height with disk bulging in L2/3 and nitric oxide in L5/S1. Surgical procedure: Decompression of the stenoses in L3/4 and L4/5 via laminectomy L4 and dynamic stabilization with Cosmic L3–5. Follow-up: After an initial period of pain relief, the patient complained of deep-seated back pain that responded to infiltration of the sacroiliac joints. After a second period of pain relief, the patient developed left-sided sciatica radiating to the L3 dermatoma. The $T_2$-weighted MRT revealed an enhanced disk protrusion in L2/3 that led to the revision surgery: Cosmic elongation to L2, hemilaminectomy L2 on the left side, sequesterectomy, and nucleotomy. This led to significant improvement of back/leg pain

these patients, seven (i.e., 88%) had a degenerative pseudolisthesis, and seven (88%) were dynamically stabilized over two or more motion segments. Thus, a clear predominance of patients with olisthesis and/or more than one stabilized segments in the group with secondarily occurring complaints and new findings on the radiographs needing reoperation was found. The predominance of olisthesis in this setting, however, remains unclear since the main reason for reoperation in this group was not screw loosening but adjacent-level degeneration—an association which is not known yet to the best of our knowledge. The correlation of reoperations for secondarily occurring complaints and new findings on the radiographs with the number of stabilized segments is not surprising: (1) Patients who need bi- or multisegmental stabilization may be more prone to multisegmental spinal degeneration per se [10]. (2) Many patients with a degenerated lumbar spine have a scoliosis. Thereby, the possible motion (one degree of freedom) transferred via the hinged joint is reduced depending on the angle of scoliosis and the number of pedicle screws. This might reduce the dynamic aspect of the construct and thereby render the adjacent levels more prone to degeneration. (3) The longer the construct, the less dynamic it is and the more stress is transferred via adjacent levels [24].

Beside the good clinical outcome results, especially the reoperation rate of 10% during follow-up seems relatively high at first glance. So, how successful and how afflicted with complications are the alternative surgical techniques?

## Spondylodesis

After single-level spondylodesis with posterior lumbar interbody fusion (consecutive patients, retrospectively reviewed), Hosono et al. reported 14% CSF leak/wound problems/hematoma, 17% transient, and 7.5% permanent neurological deficits, respectively [13]. Fritzell et al.—who compared three different techniques of lumbar fusion for chronic low back pain (noninstrumented posterolateral fusion, instrumented posterolateral fusion, and instrumented fusion with autologous interbody bone graft) in a prospective randomized study—achieved a *complication rate* of 12–40% and a *reoperation rate* of 6–22% depending on the technicality of the surgical procedure [8]. Fairbank et al. reported in a randomized controlled trial 11 out of 139 patients (8%) who needed further surgery during a follow-up of 2 years after lumbar fusion for chronic low back pain [7]. In a systematic review of 25 studies, Carreon et al. reported a *mean change of ODI* of 18.3 (range 2.1–47.0) after fusion for symptomatic lumbar degenerative disease and 27.6% revisions [4]. After lumbar fusion surgery for chronic back pain, only 25–63% rated the treatment as a success [19]. Ghiselli et al. identified in a retrospective analysis of 215 patients that 27.4% needed further surgery (decompression/arthrodesis) due to *degeneration at an adjacent level* during follow-up (mean FU, 6.7 years) [10]. Kaplan–Meier analysis suggested that 16.5% of patients will need a second operation at the adjacent level within 5 years and even 36.1% within 10 years after posterior lumbar fusion.

## Dynamic stabilization

The literature on dynamic stabilization is much less extensive and consists mainly of dynamic neutralization. After dynamic neutralization with Dynesis (IDE clinical trial, 101 patients, 1-year follow-up), Welch et al. reported promising clinical results with a *mean change in ODI* (ΔODI) of 29.3 and an improvement of leg pain (Δ54.8) and back pain (Δ24.6) [30]. Thirteen *reinterventions* related to the spine or to the initial surgery were necessary (three immediate and 10 delayed). The clinical outcome results of Stoll et al. (83 patients, mean follow-up 38.1 months) concerning ODI leg/back pain are comparable [27]. Surgery-related *complications* occurred in 11%. Early reoperation was necessary in 5%, reoperation during follow-up in 14% of patients. Thereby, seven cases (i.e., 8%) needed further surgery for *adjacent segment degeneration*. Less favorable were the results of Würgler-Hauri et al. (37 patients; prospective, consecutive; 1-year follow-up) after dynamic neutralization and decompression for stenosis, instability, and degenerative disk disease, respectively: Average lumbar pain even deteriorated from 41% to 48% during follow-up, 27% of the patients describe a fair/poor outcome, and 19% needed revision surgery within 1 year (four broken screws and two loosened systems) [32]. Similarly poor were the results of Grob et al. after Dynesis (50 patients; retrospective, consecutive; at least 2-year follow-up): The back pain was still moderately high (4.7) 2 years after Dynesis; 33% of patients reported same/worse back pain and 27% a worse ability to do physical activity/sports, and 35% stated that the operation did not help/made complaints worse; 19% required or were scheduled for further surgery within the follow-up [12].

## Interspinous process devices

Several studies have proven at least the transient effectiveness of interspinous process devices (IPDs) for neurogenic claudication in patients with degenerative spondylolisthesis and stenosis [1, 16, 33, 34]. The reported clinical success rates (2 year follow-up) are between 60% and 70%, achieved with low complication rates (malposition, dislodgement, and spinous process fracture). Although IPDs are originally intended to avoid open decompressive surgery, some surgeons have suggested the idea of using them in conjunction with selective decompression. Kong et al. report the use of Coflex®, a dynamic IPD, in 18 patients

with spinal stenosis with/without mild segmental instability of L4/5 (was defined as degenerative spondylolisthesis grade I ($n=4$) or angular instability ($n=7$) with an intervertebral range of motion >10°). The 1-year outcome displayed significant improvement of pain (VAS) and disability (ODI) without surgical complication [14]. However, the paucity of larger series on this issue does not allow specific conclusions on the effectiveness of IPDs in stenosis with instability at present.

Taken together, clinical outcome and complication rate after dynamic stabilization with Cosmic® compares favorably with the potential alternative techniques fusion and dynamic neutralization. Reoperation rate after Cosmic® during follow-up seems comparable to the potential alternative technique fusion and dynamic neutralization. Direct comparison, however, is difficult due to differences in patient collectives, follow-up intervals, and reporting of details leading to reoperations. The same is true—in our opinion—for the frequency of adjacent-level degeneration. The results in this study were achieved in a relatively old patient population with more than 60% having had preceding operations in the respective region of the spine and with less invasiveness compared to spondylodesis [29]. The role of interspinous process devices for the treatment of spinal stenosis combined with instability needs further elucidation in the future, and the three surgical options fusion, dynamic stabilization, and interspinous distraction will have to be compared in randomized studies.

## Limitations

Finally, we are aware of certain limitations of this study: Firstly, as a prospective, consecutive observation, it lacks a control population, and the results that we have achieved in our patient collective with all its peculiarities are not directly comparable to other collectives in the literature. Secondly, longtime follow-up is still pending, although the mean follow-up in our study is clearly beyond the time after which a calcium phosphate surface has healed into the bone. At last, the achieved clinical results cannot be clearly ascribed to the implanted hardware—which was implanted due to a diagnosed painful degenerative instability—or the additional surgical procedure (e.g., decompression) alone, but are the result of the whole treatment concept.

## Conclusion

Dynamic stabilization with Cosmic® results in significant improvement of pain, related disability, mental/physical health and mobility, and a high rate of satisfied patients. This can be achieved without new neurological deficits or implant breakage during follow-up. Patients with monosegmental instability seem the ideal candidates for this procedure, whereas patients with degenerative pseudolisthesis and/or bi- or trisegmental disease do worse in respect to the need of secondary surgery. A reoperation rate of 10% during follow-up seems relatively high at first glance, however, is comparable to the alternative techniques fusion and dynamic neutralization—bearing in mind the limitations of comparability from study to study. In order to further evaluate this promising technique, a prospective randomized trial (spondylodesis vs. dynamic stabilization) based on these findings is currently initialized.

**Disclosure** The senior author is a consultant of Ulrich Medical. The first author (MS) and the senior author (BM) have given lectures invited by Ulrich Medical on dynamic stabilization for which they have received fees. Above that, the authors have no financial interest in the subject under discussion.

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## Comments

This is an interesting study about non-fusion transpedicular stabilization of (thoraco-)lumbar degenerative instability, observing 100 patients prospectively with a mean follow-up of 15 months. Clinical results were in line with historical control groups of "traditional" fusion techniques from the literature, yet the overall revision rate in the current study with around 20% within 15 months seems high. Longer follow-up observation and comparative studies are required to evaluate cautiously these preliminary results of a non-fusion stabilization.

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This article verses both an interesting and pertinent clinical issue, of considerable impact in the present days, the usefulness of dynamic stabilization in the treatment of degenerative lumbar disease. The authors describe their experience with the use of one specific pedicle screw-based dynamic stabilization system (Cosmic).

There is an overall lack for clear-cut evidence for the comparative (and at times absolute) benefit of many of the surgical strategies and mechanical systems in use in the treatment of degenerative disease of the lumbar spine. There are two main reasons for this to happen. One is that only too often the patient population is not conveniently typified, and patients with different biomechanical problems contributing to the pain are included in the same treatment plan. This selection problem stems of course from an even more vast and complex issue, which is that of the interpretation for the possible causes of pain and the biomechanical mechanisms underlying it as well as the bias in the treatment solutions recommended by different surgeons.

Dynamic stabilization using either pedicle-based technology or interspinous devices seems to play a non-negligible role in mitigating pain resulting from lumbar degenerative disk disease. This argument is all the more important since these surgical solutions can be selectively used as alternatives both to fusion and total arthroplasty.

In the current series, there were a relatively significant number of reoperations due to progression of adjacent-level disease. It is unclear how this relates to the use of the Cosmic technology. In fact, it may be due to the fact that some of these patients had multisegmental stabilization procedures, as stated by the authors, a sign of more complex and extended degenerative disease where problems of coronal and sagital balance may become more stringent.

A longer follow-up period would be recommended in order to assess the long-term efficacy in pain control and quality of life improvement.

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