DOI: 10.3171/2011.3.SPINE0969

Nonfusion stabilization of the degenerative lumbar spine

Clinical article

Alberto Maleci, M.D.,[1] Rafael Donatus Sambale, M.D.,[2] Michele Schiavone, M.D.,[3] Franz Lamp, M.D.,[4] Fahir Özer, M.D.,[5] and Archibald von Strempel, M.D., D.Eng.[6]

[1]Dipartimento di Scienze Neurologiche e Cardiovascolari, University of Cagliari; [3]Ospedali Riuniti Azienda Ospedaliera Universitaria di Foggi, Foggia, Italy; [2]Wirbelsäulenchirurgie mit Querschnittgelähmtenzentrum, Orthopädische Klinik Hessisch Lichtenau, Germany; [4]Neurochirurgischen Abteilung, Krankenanstalt, Wien; [6]Department for Orthopaedic Surgery, Academic Teaching Hospital Feldkirch, Austria; and [5]Department of Neurosurgery, Vehbi Koç Foundation American Hospital, Istanbul, Turkey

Object. The goal of this study was to assess whether a stable but nonrigid nonfusion implant can stabilize the spine in degenerative diseases and also prevent instability following decompression. Instrumented spondylodesis is a recognized surgical treatment in degenerative disease of the lumbar spine. However, pain can develop at the bone graft donor site and the operative trauma can be very stressful in elderly patients, and it is suspected that there may be increased degenerative changes in the adjacent segments. In 2002, a nonrigid but rotationally stable pedicle screw and rod system was introduced, which could be used without additional fusion (referred to hereafter as the Cosmic system).

Methods. A total of 139 patients with degenerative disease of the lumbar spine underwent spinal stabilization with the Cosmic system without additional spondylodesis. Seventy patients had an additional decompression. The minimum follow-up was 2 years. The perioperative course, the clinical results, and the erect anteroposterior and lateral radiographs were recorded and compared with the preoperative data. The data were obtained from 6 different spine centers in Europe and documented on an Internet platform.

Results. The Oswestry Disability Index score improved from 48.9% to 22.5%, and the visual analog scale score decreased from 7.3 to 2.5. Lumbar lordosis did not change, nor did the adjacent disc height. Eleven patients underwent revision, 4 of them for implant failure. Of the 139 patients, 110 assessed the result as excellent, very good, or good; 24 as fair; and 5 as poor. A total of 122 patients would undergo surgery again. There were no significant differences between patients with or without an additional decompression.

Conclusions. The Cosmic system is a stable but nonrigid posterior nonfusion system. Implant complications are low and the clinical outcome is good. Longer follow-up is necessary to confirm the 2-year results.
(DOI: 10.3171/2011.3.SPINE0969)

Key Words • **low-back pain** • **lumbar vertebrae** • **spinal disease** • **spinal fusion**

Degenerative disease of the lumbar spine affects adults in middle and advanced age. Pain is the leading symptom and occurs as low-back pain, unilateral or bilateral sciatica, and as combined lumbar and sciatic pain. In the vast majority of cases, conservative methods are appropriate to treat the symptoms successfully.

If severe symptoms persist, and can no longer be tolerated by the patient, an operative procedure is indicated. There are no definite surgical modes of approach. A fundamental distinction can be made between decompression and stabilization measures or a combination of the two. The standard stabilizing procedure comprises posterolateral and/or intervertebral body and/or 360° fusion, with or without implants. Clinical success is apparently independent of the chosen type of fusion.[6]

Fusion of one or more segments of the spine, however, involves a few possible side effects: longer-lasting pain over the cancellous bone graft donor site; prolonged operation time; increased blood loss; increased risk of degenerative changes in neighboring segments; sacroiliac joint–related pain, particularly with lumbosacral spondylodesis; and definitive destruction of vertebral segments.

Abbreviations used in this paper: AP = anteroposterior; IVS = intervertebral space; ODI = Oswestry Disability Index; PLF = posterolateral fusion; PLIF = posterior lumbar interbody fusion; VAS = visual analog scale.

This article contains some figures that are displayed in color online but in black and white in the print edition.

If the spondylodesis is performed in conjunction with implants, the rate of fusion is said to be increased compared with a procedure without implants.[1] The use of stable implants without additional spondylodesis is a new way of treating degenerative instability. The precondition is that the implant has adequate stability without being rigid, to avoid screw loosening or implant fracture and to ensure that good screw fixation in the bone is guaranteed.

Von Strempel et al.[27] introduced a pedicle screw-rod system with an articulated screw, which has a hinged joint between the screw head and the threaded part. In this way, a division of the load between the implant and the anterior spine is achieved.[10] Comparative analyses of stability showed that the same rotational stability is achieved with the hinged screw as with an intact vertebral segment.[26] In 2002 the threaded part of the screw was given a hydroxyapatite coating for better bone ingrowth, and the system has been used since then without additional fusion.[28]

Due to the good initial clinical and radiological results, a study group was formed in May 2004 consisting of 6 spine surgeons from 6 different orthopedic or neurosurgical centers to find out whether it is possible to achieve good clinical results without additional fusion. In this case, a surgical alternative would be available that entailed less operative trauma and avoided possible pain over the bone graft donor site.

Methods

A posterior nonfusion implant system that can function without protection from spondylodesis should not have any rigid characteristics. However, to be able to control instabilities effectively, the system must also feature stable characteristics. Human cadaver tests demonstrated that the system allows 30%–40% of flexion-extension and the same rotational stability as the intact spine.[25] The same was shown by spine tests conducted in calves. The Cosmic system allows the same rotation stability as a healthy motion segment.[24] The Cosmic system (Fig. 1) is a stable nonrigid implant made from a titanium alloy (Ti 90%, Al 6%, V 4%). Stability is assured by using a 6.25-mm-diameter rod of varying lengths. Nonrigidity is assured by using a hinged screw, which comes in 2 different widths (outer diameter 6 mm, inner diameter 4 mm, or outer diameter 7 mm, inner diameter 5 mm), with lengths ranging from 30 to 55 mm. The screw features a hinged joint between its head and the threaded section, which causes the load to be shared between the implant system and anterior vertebral column. Compared with a rigid system, the hinged screw device permits a greater load through the disc and allows for greater axial displacement without any decrease of rotational instability.[10] Load sharing and axial displacement are important factors for the long-term survival of the implant as well as for the preservation of the pump function (shock absorber function) of the disc. Due to this dynamic stabilization, we expect a better protection of adjacent segments against increased degeneration. In a cyclic loading test with 0.3–3.0 kN/Hz, we did not find an implant breakage or any wear debris after 10 million cycles.[4] Because the Cosmic system is used like a stability endoprosthesis, the bone healing of

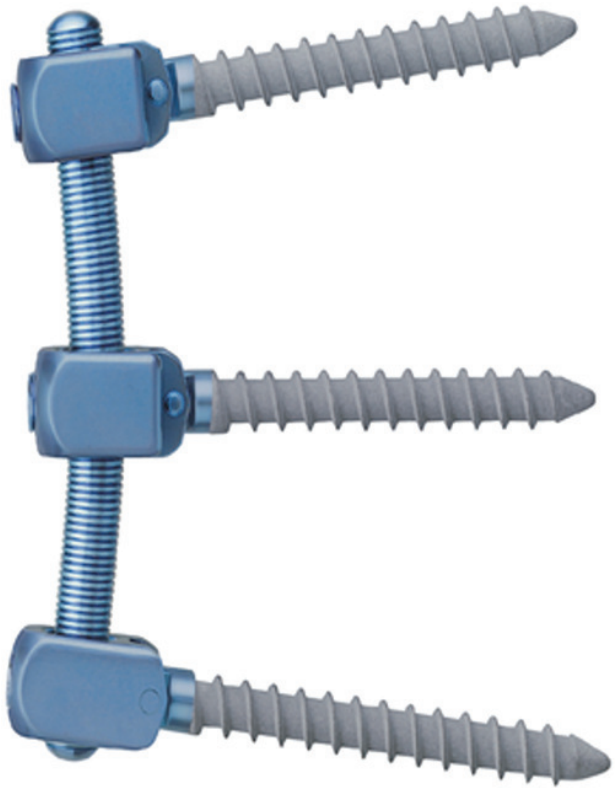

Fig. 1. The Cosmic system. Reprinted with permission from ulrich medical.

the pedicle screws is of major importance. For this reason, the threaded part of the screw is coated with "Bonit." Bonit is the second generation of bioactive calcium phosphate coatings on implants, which was used for the first time (in 1995) in oral surgery for dental implants.[18] There exists a study in the field of spinal surgery on the use of the first generation of bioactive calcium phosphate–coated Schanz screws. In this study it was found that there was a significantly improved fixation of the coated screws in comparison with the uncoated screws.[24]

The system was tested in the laboratory beforehand and was also tested clinically by Scifert et al.,[26] Goel et al.,[10] Ettinger,[4] von Strempel et al.,[28] and Schmoelz et al.[25]

Operative Technique

The patient is positioned so that his or her lumbar lordosis is maintained. The approach to the lumbar spine is through a midline incision. Under lateral and AP image intensifier control, the pedicle screws are first implanted. A bicortical position of the screw in the sacrum is desirable.

To achieve maximum press-fit of the screw in the pedicle and vertebral body, the pedicle is drilled with a 3.2-mm drill and the screw is then implanted. In very hard cancellous bone and in the sacrum, the thread tap is used first. Before the rods are implanted, the patient has to be checked for good lordotic position. Straight rods are implanted in the case of 1-segment use, and lordotically curved rods for 2- and 3-segment use; the instrumentation

of more than 3 segments is not recommended. No correction or reduction is performed. If necessary, adequate decompression is performed; this may involve a laminectomy with medial facetectomy. In the case of pure lumbar pain caused by discogenic pain or painful facet joint arthritis, only stabilization is performed.

Moderate distraction of up to 4 mm is possible to expand the neural foramina. When decompression is necessary, a transverse stabilizer can be mounted additionally.

After copious irrigation, a 12-mm suction drain is inserted and the wound is closed in layers. Mobilization commences on the 1st or 2nd postoperative day after removal of the wound drain. An external support is not prescribed. The patients are told to avoid physical exertion for 6 weeks.

Between May 2004 and January 2005, 139 patients underwent spinal stabilization; these patients had at least 2 years of follow-up. No institutional review board approval was necessary because no additional clinical investigations were performed. The patients gave approval for the use of their blinded data. Of this group, 70 patients also had decompression. The patients were treated in 6 different departments (Ospedale Marino, Neurosurgery Department, Cagliari, Italy; Orthopädische Kliniken Lichtenau, Germany; Krankenhaus Neunkirchen, Orthopädie/Unfallchirurgie, Neunkirchen, Austria; Ospedale Vittorio Emanuele, Orthopedic Department, Bisceglie, Italy; American Hospital, Neurosurgery Department, Istanbul, Turkey; and Landeskrankenhaus Feldkirch, Orthopedic Department, Feldkirch, Austria). This surgery had been preceded by failed conservative treatment. The basic indications were lumbar pain and lumbar-sciatic pain as well as neurogenic claudication (Fig. 2A). For a better assessment, the indication survey is presented in Table 1.

TABLE 1: Indication data in 139 patients with degenerative spine disease

Main Indication & Decompression Status	No. of Patients
w/o decompression	
degenerative disc disease	46
osteochondrosis/spondyloarthrosis	23
w/ decompression	
spinal stenosis	61
spondylolisthesis	9

Contraindications were stabilizations that extended more than 3 levels. All patients underwent MR imaging or CT scanning in addition to preoperative radiological examination.

Preoperative Patient Data

The following details were documented in each patient: age, sex, weight, ODI activity score, and 10-point VAS score.

Preoperative Radiography and Neuroimaging Investigations

Standard erect AP and lateral radiographs were obtained in all patients, together with an MR imaging study (or a CT scan if MR imaging was not feasible due to claustrophobia, cardiac pacemaker, and so on).

The following measurements were made on the radiograph: lumbar lordosis between the superior surface of L-1 and the superior surface of S-1, segmental lordosis in the segment(s) to be treated between the superior surface of the cranial instrumented vertebra and the inferior surface of the caudal instrumented vertebra, along with

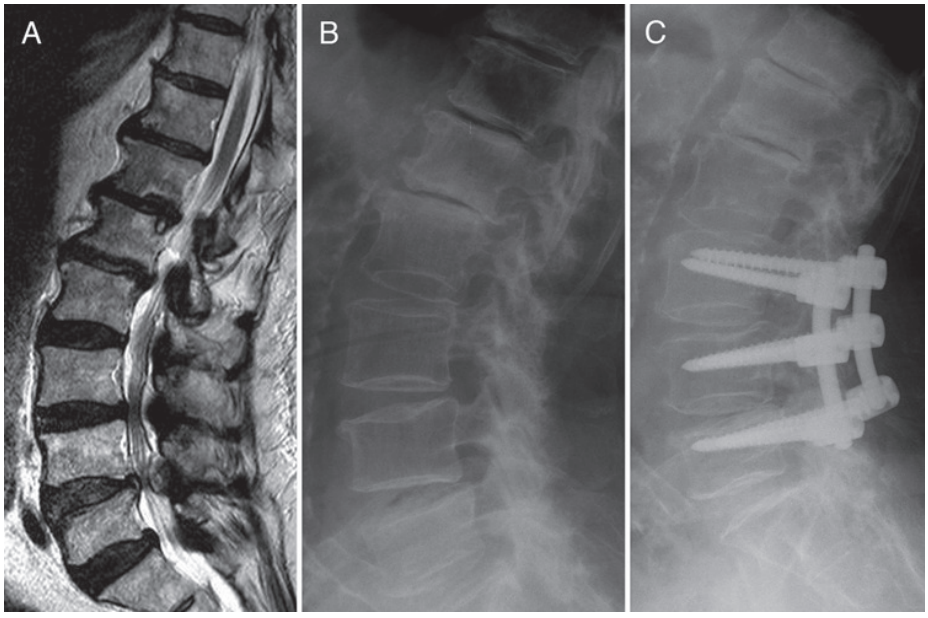

Fig. 2. A and B: Preoperative MR imaging study **(A)** and preoperative radiograph **(B)** obtained in a 68-year-old man with spinal stenosis in L3–4 and L4–5. **C:** Postoperative radiograph obtained in the same patient after instrumentation with the Cosmic system at L3–4 and L4–5 and decompression.

measurement of the height of the IVS in the segment adjacent to the instrumentation. A formula has been used to correct the radiographic magnification effect at a different film focal distance (IVS = ((a+b)/2)/H).

Perioperative Data Capture

The following data were documented: duration of the operation from incision to skin suture, intra- and postoperative transfusion of autologous or donor blood, duration of hospitalization, implant-related complications, and necessary revisions, with the reasons stated. In addition, it was possible to comment on the perioperative course (see Fig. 2).

Follow-Up Examination

After a follow-up duration of at least 2 years, the ODI activity score was again measured, along with the pain intensity according to the 10-point VAS score. Revisions that were performed between discharge from hospital and the follow-up date were documented, together with the reason for the revision. In addition, the patients were asked if they would undergo the operation again and how they assessed its success. The classification is made according to a grading system very similar to those used in German and Austrian schools. The patients received this form together with the ODI and VAS questionnaire to display their personal estimation of clinical outcome. The possible grades in the questionnaire were as follows: 1, excellent; 2, very good; 3, good; 4, fair; and 5, poor.

Radiological Follow-Up

Erect AP and lateral radiographs were taken again after the spine surgery, both prior to discharge from hospital and after 2 years. The lumbar lordosis and lordosis in the instrumented vertebral segment(s) were measured, along with the height of the IVS in the neighboring segment (according to the above-mentioned formula to correct the magnification effect of the radiograph). Implant failure and irregular radiological findings such as radiolucent areas were also documented.

Statistical Investigation

The captured data of the Cosmic multicenter trial was submitted through an online portal secured by a password. The participants entered their personal data over this portal into the database, which was administered with Microsoft Access. The statistical analysis for the descriptive data were evaluated using Microsoft Access and Microsoft Excel. The absolute and relative frequencies in the pool of descriptive statistical data were shown and divided into 2 major subgroups. Every codomain was shown with the measures of central tendency, which were defined as follows: minimum, maximum, the mean values, and respective median values. For the declaration of the spread, the SD and the interquartile range was chosen. For the depiction of the diagrams including absolute frequencies, concrete quantities, discrete and/or consistent data as well as for rating attributes, histograms were used. In the area of applied statistics, the Pearson correlation coefficient was used to verify the probability of connections between data sets; no clear correlation was found. The main interesting correlation was the combination of the patient data (age, weight, sex, and so on) and the postoperative data on quality of life and pain intensity (ODI, VAS, hospital stay, and so on).

The data capture ended after reaching 185 patients with 24 months of follow-up. For final evaluation, the investigators decided to exclude 24 patients who underwent the Cosmic instrumentation in combination with a fusion. Furthermore, 22 patients were lost to follow-up. These patients could not be seen for the follow-up examination, for different reasons.

Results

Of the 139 patients who had completed the follow-up period of at least 2 years, 69 were given stabilization in which the Cosmic system was used without additional decompression, and 70 were provided with stabilization with additional decompression. A total of 683 screws and 278 rods, including 29 crossbars, were implanted. Of the patients who received no additional decompression, 30% had undergone previous surgery. Of the patients who received additional decompression, 26% had previously undergone surgery. Table 2 shows the patient data distribution, and Table 3 shows the perioperative data distribution.

More than 90% of the patients were given implants for 1 or 2 segments. The most frequently affected segments (L4–5 and L5–S1) included 57 patients with and 50 without decompression. Only 10 patients received perioperative transfusions of their own or donor blood. The clinical results after 2 years of follow-up (Table 4) were analyzed using the ODI scores and the 10-point VAS. The patients without decompression showed an improvement of 49.3% to 24.5% after 2 years, whereas those with decompression showed improvement from 48.7% to 20.6%. The results remained constant between 12 and 24 months after surgery (Fig. 3).

In the patients without decompression, pain decreased from 7.4 to 2.4 on the 10-point VAS, and in those with decompression it decreased from 7.1 to 2.7 (Fig. 3). In this case as well, the results remained constant between 12 and 24 months after surgery; thus, the differences between the 2 groups were not significant.

In the group without decompression, lumbar lordosis

TABLE 2: Survey of data in 139 patients with degenerative spine disease*

Characteristic	Patients w/ Decompression	Patients w/o Decompression
no. of male patients (%)	29 (42)	33 (47)
no. of female patients (%)	40 (58)	37 (53)
age in yrs		
median	53.0	56.0
IQR	23.5	22.0
weight in kg		
median	73.0	74.0
IQR	17.5	17.0

* IQR = interquartile range.

TABLE 3: Survey of perioperative values in 139 patients with degenerative spine disease

Periop Data	Patients w/ Decompression	Patients w/o Decompression
no. of instrumented levels (%)		
L2–3	7 (6.7)	2 (2.1)
L3–4	27 (25.7)	7 (7.3)
L4–5	57 (54.3)	50 (52.1)
L5–S1	14 (13.3)	37 (38.5)
op time in mins		
median	115.0	126.0
IQR	57.5	42.0
hospital stay in days		
median	8.0	8.0
IQR	4.5	4.0

was 50.0° before surgery and 48.4° after 2 years. In the group with decompression, it was 48.7° and 47.1°, respectively. The results 12–24 months after surgery remained constant. Minor differences between the groups were not significant.

In the group without decompression, the alpha angle, measured in the instrumented segments, was 12.5° before surgery and 11.9° after 2 years. In the group with decompression, the alpha angle was 13.9° before surgery and 13.8° after 2 years. The results at the 1- and 2-year follow-up examinations remained constant. The measurements of the lordosis in the lumbar spine and the alpha angle showed that during the period under review there was no decrease in the height of the intervertebral discs, which in the case of the joint end screw would lead to a decrease in the lordosis and the alpha angle.

TABLE 4: Survey of clinical results in 139 patients with degenerative spine disease

Postop Data*	Patients w/ Decompression	Patients w/o Decompression
ODI improvement		
median	30%	29%
IQR	24%	23%
VAS improvement		
median	5 points	6 points
IQR	2 points	2 points
lumbar lordosis difference		
median	1°	1°
IQR	37°	18.5°
alpha angle difference		
median	1°	1°
IQR	11°	9°
IVS difference		
median	0.019°	0.035°
IQR	0.1101°	0.115°

* Data obtained at 24-month follow-up.

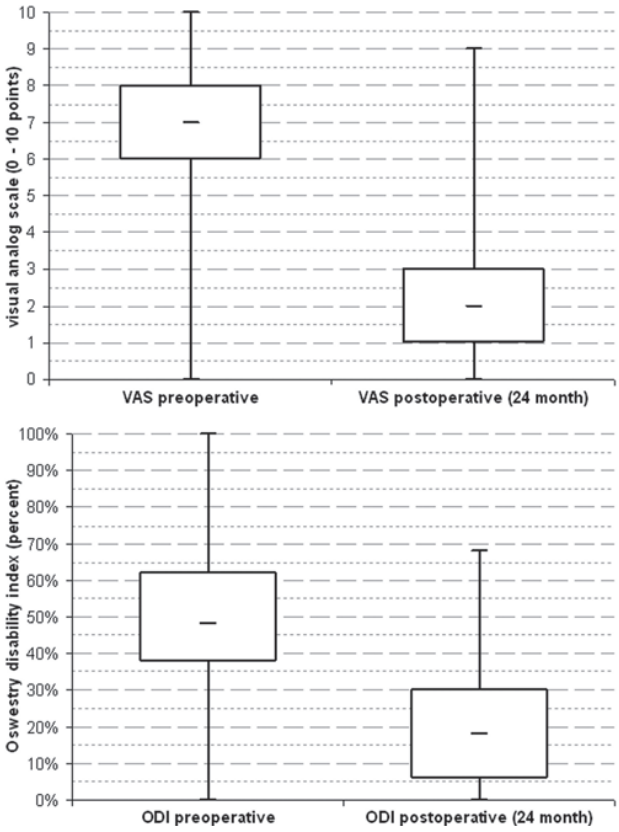

Fig. 3. Box plots showing pre- and postoperative quality-of-life **(upper)** and pain **(lower)** scores.

Of the 70 patients in the group with decompression, 28 had a spondylolisthesis (true [arising in childhood] or false [arising in adulthood]) as a cause for the spinal stenosis. Even in these patients, the lumbar lordosis and the alpha angle were still stable after 2 years.

The intervertebral height (also called the IVS) in the cranially adjacent segment remained constant even after 2 years; this was true of the average values as well as the relevant individual values.

Two years after the intervention, the patients were asked how they rated the success of the surgery and whether they would undergo such an operation again. Only 3 patients who had not received additional decompression, and 2 patients who had, gave the operation a poor rating. Accordingly, 87% of the patients without additional decompression and 89% of patients with additional decompression would have the operation again (Fig. 4).

Of the 69 patients who had not received additional decompression, 3 underwent further surgery during the period under review: 2 due to a deep infection, and the third due to painful instability in an adjacent segment. In 1 patient a screw breakage without clinical symptoms was radiologically documented; no corrective surgery was performed. In 5 other patients, radiolucent areas around the threads of the screws were documented. The patients experienced no symptoms, and no corrective surgery was performed.

In the 70 patients who received additional decompression, 8 corrective surgeries were performed: 3 due to deep

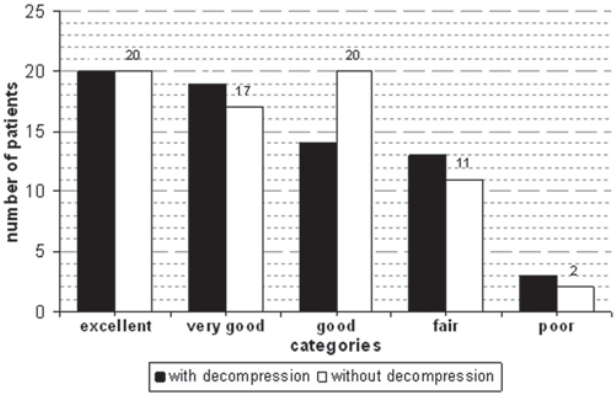

Fig. 4. Bar graph showing results of the patient self-assessment question.

infections, 1 due to hematoma formation, 1 due to a broken screw together with loose screws, 2 due to loosening of a screw, and 1 due to an osteoporotic fracture cranially to the instrumentation. In 3 other patients, radiolucent areas around the threads of the screws were documented; there were no clinical symptoms and no corrective surgery was performed. No screw dislocations were found in either of the 2 groups. No wear debris could be found in the revision cases. An evaluation of a possible correlation between the groups with different indications and the loosening or failure of implants generated no interrelation.

Genuine correlations between patient data and the results were not found in the group of patients with or without additional decompression. There were statistical trends between the ages of the patients and a higher rating on the VAS as well as the length of hospital stay. This applies to the groups with or without additional decompression.

There has also been a statistical trend between the length of the hospital stay and a lower ODI score in the group of patients without additional decompression. In the group of patients with additional decompression, a statistical trend between the ages of the patients and a lower ODI score was found.

Discussion

The surgical treatment of therapy-resistant lumbar sciatic pain is traditionally performed by spinal fusion with or without instrumentation. A fusion is still considered to be the gold standard, and the results of treatments completed using alternative methods must therefore be measured against those achieved with fusion.

The aim of the treatment fusing painful spinal motion segments is to eliminate movements that cause pain in the segment by stiffening. If in addition sciatic pain is caused by lateral or central stenosis, sufficient decompression is applied.

The same operational objectives are pursued with the Cosmic system—elimination of painful movements and sufficient stabilization, with additional decompression.

Whereas in fusion with instrumentation, implants are relieved by the spinal fusion that occurs, this protection does not exist for the Cosmic system. For this reason, the screw head is not rigidly connected to the threaded part, but semirigidly connected via a hinged joint. The threaded part is coated with Bonit to improve the anchoring in the bone.[24]

After 2 years, our results showed an improvement in the ODI score from 49.3% to 24.5% (group without decompression) or from 48.7% to 20.6% (group with decompression), and a decrease in pain from 7.4 to 2.4 points (group without decompression) or from 7.1 to 2.7 points (group with decompression). Because this was not a randomized study, we compared the clinical results after a spinal fusion in the literature with our own, and found that our results lie within the middle to upper third. Niemeyer et al.[21] found that the ODI score improved from 56.8% to 31.2% and the pain (based on the VAS) decreased from 8.3 to 4.8 points in 54 patients 2–5 years after a 360° spinal fusion.

Madan and Boeree[19] found that the ODI score had dropped to less than 30% after 2 years in 54 of their 74 patients. Glassman et al.[9] found that the ODI score was 22.2% in their 497 patients after 1 or 2 years. With a brief follow-up in 34 patients 6–12 months later, Deutsch and Musacchio[3] found that the ODI score had improved from 57% to 29%, and the pain had decreased from 8.1 to 1.4 points on the pain scale.

After PLF with instrumentation in 132 patients and a follow-up period lasting between 5.5 and 19.4 years, Wenger et al.[29] found that back pain had decreased to 2.13 points and leg pain had dropped to 1.59 points.

When assessing the clinical results from a self-evaluation by the patients, the results in our study were found to be in the middle to upper third—76.8% in the group without decompression and 81.5% in the group with decompression evaluated their results as good, very good, or excellent; 18.8% and 15.7% as fair; and only 4.3% and 2.1% as poor, respectively.

In a comparison study between patients with PLF and those with PLIF, Madan and Boeree[20] found that the clinical results were poor: 14.3% and 34.5%, respectively. Five years after a 360° fusion, Freeman et al.[5] found the results for 83% of the patients to be very good. After 10 years, Brantigan et al.[2] found that the results for 87.8% of their patients were excellent or good. All together, 93.1% of the patients were satisfied, although 23 of these had to undergo a further operation in the area of the lumbar spine.

Kim et al.[14] similarly found good results in a prospective study of 167 patients in which 3 different fusion methods (PLF, PLIF, and PLF plus PLIF) were compared, with 80.7% good and very good results after PLF, 87.8% after PLIF, and 85.5% after PLF plus PLIF.

In our study, 87% of the patients in the group without decompression and 89% in the group with decompression would undergo the operations again 2 years after the Cosmic operation.

All together, complications were found in 14.5% of patients in the group without decompression and in 17.1% of those in the group with decompression after 2 years. Of these complications, 4.4% of patients had to undergo repeat surgery in the group without decompression, and 11.4% had to undergo repeat surgery in the group with decompression. With both groups together, repeat surgery was necessary in 5 cases (3.6%) because of infection, in 2 cases (1.4%) due to a loose or broken screw, and in 3 cases

(2.2%) because of secondary problems (instability in the adjacent segment, stenosis in the adjacent segment, and osteoporotic fracture in the adjacent segment).

In total, radiological peculiarities with the implants were found in 13 patients: broken screws accounted for 2 cases, in 1 of which repeat surgery was needed; radiolucent areas around the screws appeared in 11 cases, 2 of which led to repeat surgery, and in the detachment of the rod-screw connection, which also led to repeat surgery in 1 case. In the other case with a screw fracture as well as in other cases with radiolucent areas around the screws, there were no complaints of any symptoms and therefore no repeat surgery was needed. No neurological complications appeared during the observation period.

Of 105 patients, Jutte and Castelein[13] found 54% with complications of different degrees of severity, of which 4.7% had deep infections and 12.4% involved fractured screws.

In a randomized multicenter study and 2 years' follow-up during a comparison of 3 different types of fusion (PLF, PLF with instrumentation, and 360° fusion), Fritzell et al.[7] found complications in 6% of the cases in the first group, in 16% in the second group, and in 31% in the third group. Similar good results were found in all 3 fusion groups.

In another multicenter study involving 211 patients, Fritzell and colleagues[6] found a repeat surgery rate of 6% in the group with PLF, 22% in the group with PLF with instrumentation, and approximately 17% in the group with circumferential fusion.

In a large retrospective study involving 1680 patients, Greiner-Perth et al.[11] found a repeat surgery rate of 13.2%.

Of 132 patients with PLF with instrumentation, Wenger et al.[29] found infections in 2.3% and pseudarthrosis in 5.3% of cases.

Whether using the Cosmic system produces a smaller risk of the development of degenerative changes in the adjacent segment when compared with spinal fusion is still not known after 2 years of follow-up. Measuring the height of the intervertebral discs in the cranial adjacent segment by using an equation that takes into account the effects of radiological enlargement revealed no recognizable changes after 2 years.

In the literature, the development of adjacent-segment degeneration is found to be variable after spinal fusion. In addition, Okuda et al.[22] found 29% radiologically confirmed connection degenerations, but only 4% led to repeat surgery. No risk factors could be found.

After 6 years of follow-up, Lai et al.[17] found segment degenerations in 21.7% of cases after fusion. In this study, a flattened lordosis had no effect on the connection degeneration. On the other hand, in 36.1% of the patients with radiologically confirmed degeneration in the connection segment, Kumar et al.[15] discovered that the type of fusion (PLIF carried a higher risk than PLF) and a flattened lordosis represented risks for connection degeneration. In comparison with the fusion group, the same authors[16] also discovered that less than half of the patients who had undergone operations without fusion due to degenerative discopathy showed radiological changes in the adjacent segment.

Helenius et al.[12] also found degenerative changes in the nonfused lumbar spine in 22% of cases after a follow-up of more than 20 years in patients who had undergone operations for scoliosis rather than painful degenerative changes. In total, 13% of the patients had lower-back pain.

In a literature review, Park et al.[23] discovered that the rate of symptomatic connection instabilities in patients who had undergone transpedicular fusion with instrumentation was higher than in those without instrumentation (12.2% compared with 5.6%).

For 250 patients after posterior fusion with an average follow-up lasting 6.7 years, Ghiselli et al.[8] found connection degeneration with the need for repeat surgery in 27.4% of cases.

It can be assumed that fused sections of the spinal column remain stable in their position when pseudarthrosis is not present.

When using the Cosmic system there is no fusion, so the question of stability after 2 years is of particular importance. When compared with the preoperative values, both the lumbar lordosis measured from the base plate L-1 to the cover plate S-1 as well as the alpha angle measured in the segments with instrumentation remained stable after 2 years. This also applied to the group of patients in whom spondylolisthesis was diagnosed (28% of patients in the study).

These angles were measured on radiographs of the lumbar spine AP and lateral in the stand. To verify the stability, we have not used a function radiograph, because these are obtained in the lateral position and their results can be greatly influenced by muscle spasms in certain cases when there are complaints.

All together our data show that nonfusion surgery using the Cosmic system is a relatively simple and safe procedure; it can be considered as effective as fusion procedure results (from the literature) in relieving pain in patients affected by lumbar degenerative disease. A longer follow-up will provide information about its ability to preserve the lumbar spine at levels adjacent to the operated ones.

Conclusions

The Cosmic system is a pedicle screw-rod system used for surgical stabilization of therapy-resistant lower-back pain and lumbar radiculopathies without having to perform a spinal fusion. After 2 years, the clinical results were found to be comparable to those achieved with spinal fusions published in the literature. The complication rate, including complications in relation to the implant, is equivalent to the lower to middle third of complications reported after spinal fusion.

When using the Cosmic system, attention to the contraindications is essential. No more than 3 segments may be stabilized, and stabilization must only be performed in situ, where slight distractions up to 4 mm in the segment are permissible.

Stabilization with the Cosmic system without spinal fusion offers the following advantages: a reduction in surgical trauma, avoidance of pain via the bone graft extraction site, and preservation of the intervertebral cartilage, retaining this structure's damping function. Spontaneous

fusions were not noted during the observation period, but it is assumed that the stabilization will cause fibrous rigidity over time.

No reduction in height of the intervertebral cartilage of the adjacent segments was found after 2 years. The question of whether the risk of connection-segment instabilities can be reduced with Cosmic stabilization in comparison with fusions can only be answered after a longer follow-up.

Disclosure

This work was supported by corporate funds from Ulrich Medical, Ulm, Germany.

Author contributions to the study and manuscript preparation include the following. Conception and design: Maleci, von Strempel. Acquisition of data: all authors. Analysis and interpretation of data: Maleci, von Strempel. Drafting the article: von Strempel. Critically revising the article: Maleci, von Strempel. Reviewed final version of the manuscript and approved it for submission: all authors.

References

1. Boos N, Webb JK: Pedicle screw fixation in spinal disorders: a European view. **Eur Spine J 6:**2–18, 1997
2. Brantigan JW, Neidre A, Toohey JS: The Lumbar I/F Cage for posterior lumbar interbody fusion with the variable screw placement system: 10-year results of a Food and Drug Administration clinical trial. **Spine J 4:**681–688, 2004
3. Deutsch H, Musacchio MJ Jr: Minimally invasive transforaminal lumbar interbody fusion with unilateral pedicle screw fixation. **Neurosurg Focus 20(3):**E10, 2006
4. Ettinger C: **Test Report No. 27.011019.30.95.** Rosenheim, Germany: Endolab Mechanical Engineering, 2002, pp 1–7
5. Freeman BJ, Licina P, Mehdian SH: Posterior lumbar interbody fusion combined with instrumented postero-lateral fusion: 5-year results in 60 patients. **Eur Spine J 9:**42–46, 2000
6. Fritzell P, Hägg O, Nordwall A: Complications in lumbar fusion surgery for chronic low back pain: comparison of three surgical techniques used in a prospective randomized study. A report from the Swedish Lumbar Spine Study Group. **Eur Spine J 12:**178–189, 2003
7. Fritzell P, Hägg O, Wessberg P, Nordwall A, Swedish Lumbar Spine Study Group: Chronic low back pain and fusion: a comparison of three surgical techniques: a prospective multicenter randomized study from the Swedish Lumbar Spine Study Group. **Spine (Phila Pa 1976) 27:**1131–1141, 2002
8. Ghiselli G, Wang JC, Bhatia NN, Hsu WK, Dawson EG: Adjacent segment degeneration in the lumbar spine. **J Bone Joint Surg Am 86-A:**1497–1503, 2004
9. Glassman S, Gornet MF, Branch C, Polly D Jr, Peloza J, Schwender JD, et al: MOS short form 36 and Oswestry Disability Index outcomes in lumbar fusion: a multicenter experience. **Spine J 6:**21–26, 2006
10. Goel VK, Konz RJ, Chang HT, Grosland NM, Grobler LJ, Chesmel KD: Hinged-dynamic posterior device permits greater loads on the graft and similar stability as compared with its equivalent rigid device: a three-dimensional finite element assessment. **JPO 13:**17–20, 2001
11. Greiner-Perth R, Boehm H, Allam Y, Elsaghir H, Franke J: Reoperation rate after instrumented posterior lumbar interbody fusion: a report on 1680 cases. **Spine (Phila Pa 1976) 29:**2516–2520, 2004
12. Helenius I, Remes V, Yrjönen T, Ylikoski M, Schlenzka D, Helenius M, et al: Comparison of long-term functional and radiologic outcomes after Harrington instrumentation and spondylodesis in adolescent idiopathic scoliosis: a review of 78 patients. **Spine (Phila Pa 1976) 27:**176–180, 2002
13. Jutte PC, Castelein RM: Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations. **Eur Spine J 11:**594–598, 2002
14. Kim KT, Lee SH, Lee YH, Bae SC, Suk KS: Clinical outcomes of 3 fusion methods through the posterior approach in the lumbar spine. **Spine (Phila Pa 1976) 31:**1351–1358, 2006
15. Kumar MN, Baklanov A, Chopin D: Correlation between sagittal plane changes and adjacent segment degeneration following lumbar spine fusion. **Eur Spine J 10:**314–319, 2001
16. Kumar MN, Jacquot F, Hall H: Long-term follow-up of functional outcomes and radiographic changes at adjacent levels following lumbar spine fusion for degenerative disc disease. **Eur Spine J 10:**309–313, 2001
17. Lai PL, Chen LH, Niu CC, Chen WJ: Effect of postoperative lumbar sagittal alignment on the development of adjacent instability. **J Spinal Disord Tech 17:**353–357, 2004
18. Lacefield WR: Current status of ceramic coatings for dental implants. **Implant Dent 7:**315–322, 1998
19. Madan SS, Boeree NR: Comparison of instrumented anterior interbody fusion with instrumented circumferential lumbar fusion. **Eur Spine J 12:**567–575, 2003
20. Madan SS, Boeree NR: Outcome of posterior lumbar interbody fusion versus posterolateral fusion for spondylolytic spondylolisthesis. **Spine (Phila Pa 1976) 27:**1536–1542, 2002
21. Niemeyer T, Bövingloh AS, Halm H, Liljenqvist U: Results after anterior-posterior lumbar spinal fusion: 2–5 years follow-up. **Int Orthop 28:**298–302, 2004
22. Okuda S, Iwasaki M, Miyauchi A, Aono H, Morita M, Yamamoto T: Risk factors for adjacent segment degeneration after PLIF. **Spine (Phila Pa 1976) 29:**1535–1540, 2004
23. Park P, Garton HJ, Gala VC, Hoff JT, McGillicuddy JE: Adjacent segment disease after lumbar or lumbosacral fusion: review of the literature. **Spine (Phila Pa 1976) 29:**1938–1944, 2004
24. Sandén B, Olerud C, Petrén-Mallmin M, Larsson S: Hydroxyapatite coating improves fixation of pedicle screws. A clinical study. **J Bone Joint Surg Br 84:**387–391, 2002
25. Schmoelz W, Onder U, Martin A, von Strempel A: Non-fusion instrumentation of the lumbar spine with a hinged pedicle screw rod system: an in vitro experiment. **Eur Spine J 18:**1478–1485, 2009
26. Scifert JL, Sairyo K, Goel VK, Grobler LJ, Grosland NM, Spratt KF, et al: Stability analysis of an enhanced load sharing posterior fixation device and its equivalent conventional device in a calf spine model. **Spine (Phila Pa 1976) 24:**2206–2213, 1999
27. von Strempel A, Neckritz A, de Muelenaere P, du Toit G: Dynamic versus rigid spinal implants, in Gunzberg R, Szpalski M (eds): **Lumbar Spinal Stenosis.** Philadelphia: Lippincott Williams & Wilkins, 2000, pp 275–285
28. von Strempel A, Stoss C, Moosmann D, Martin A: Non-fusion stabilization of the lumbar spine in the case of degenerative diseases with a dynamic pedicle screw rod. **Coluna/Columna 5:**27–34, 2006
29. Wenger M, Sapio N, Markwalder TM: Long-term outcome in 132 consecutive patients after posterior internal fixation and fusion for Grade I and II isthmic spondylolisthesis. **J Neurosurg Spine 2:**289–297, 2005

Manuscript submitted March 31, 2009.
Accepted March 15, 2011.
Please include this information when citing this paper: published online May 13, 2011; DOI: 10.3171/2011.3.SPINE0969.

Address correspondence to: Alberto Maleci, M.D., Scienze Chirurgiche e Trapianti d'Organo, Ospedale S. Giovanni di Dio, 09124 Cagliari, Italy. email: amaleci@unica.it.