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Evaluation of Functional Outcomes in Individuals 10 Years after Posterior Lumbar Interbody Fusion with Corundum Implants and Decompression: A Comparison of 2 Surgical Techniques

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Background: The purpose of this study was to evaluate lumbar spine-related functional disability in individuals 10 years after lumbar decompression and lumbar decompression with posterior lumbar interbody fusion (PLIF) with corundum implants surgery for degenerative stenosis and to compare the long-term outcome of these 2 surgical techniques.

Material/Methods: From 1998 to 2002, 100 patients with single-level lumbar stenosis were surgically treated. The patients were randomly divided into 2 groups that did not differ in terms of clinical or neurological symptoms. Group A consisted of 50 patients who were treated with PLIF and the use of porous ceramic corundum implants; the mean age was 57.74 and BMI was 27.34. Group B consisted of 50 patients treated with decompression by fenestration; mean age was 51.28 and the mean BMI was 28.84.

Results: There was no statistical significance regarding age, BMI, and sex. Both treatments revealed significant improvements. In group A, ODI decreased from 41.01% to 14.3% at 1 year and 16.3 at 10 years. In group B, ODI decreased from 63.8% to 18.36% at 1 year and 22.36% at 10 years. The difference between groups was statistically significant. There were no differences between the groups regarding the Rolland-Morris disability questionnaire and VAS at 1 and 10 years after surgery.

Conclusions: Long-term results evaluated according to the ODI, the Rolland-Morris disability questionnaire, and the VAS showed that the both methods significantly reduce patient disability, and this was maintained during next 10 years. The less invasive fenestration procedure was only slightly less favorable than surgical treatment of stenosis by both PLIF with corundum implants and decompression.

MeSH Keywords: **Aluminum Oxide • Decompression • Lumbar Vertebrae • Spinal Stenosis**

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Background

Spinal canal stenosis is a syndrome of various etiology, whose morphological manifestation is narrowing of the spinal canal, intervertebral foramina, and lateral recesses [1]. It is the most common cause for surgical treatment in patients over 65 years of age [2,3]. In the surgical treatment for lumbar stenosis, various methods have been applied, which have been described in the literature as PLIF (posterior lumbar interbody fusion), with or without additional transpedicular stabilization aimed at achieving the right intervertebral space and stabilizing the motor segment under treatment [4–6]. However, biomaterials were rarely applied in interbody fusion. Some authors have investigated the role of ceramic-based grafts that enable large-scale production, biocompatibility, an appropriate safety profile, and the ability to closely mimic physiological bone [7].

The aim of the study was to compare long-term results of efficacy of PLIF versus fenestration of patients with lumbar stenosis treated with:

- decompression of neural structures and interbody fusion with ceramic corundum implants, and
- fenestration without restoring intervertebral space and gaining stability.

Material and Methods

After obtaining approval by the Institutional ethics Committee, 100 patients with single-level lumbar spinal stenosis due to disc degeneration were surgically treated during the years 1998–2002.

All the patients were prospectively qualified for surgery by an experienced spine surgeon who is the chief of the Spine Surgery Department. All patients had neurological examination followed by radiological imaging (X-ray, MRI, and/or CT) to confirm the diagnosis [8]. The criteria for qualification for the groups researched were the following: severe back pain radiating to 1 or both of the legs, neurogenic claudication below 200 m, no improvement despite 3-months

of appropriate physiotherapy, and stenosis requiring resection of more than 50% of facet joints. The criteria for denying the treatment were: lack of patient consent, spondylolisthesis, and other pathological abnormalities (e.g., metastasis, infection, or fracture).

The patients underwent parallel group randomization into the 2 groups. Quasi-random allocation was performed by medical record number.

They did not differ in terms of clinical or neurological symptoms. The sample size had been assumed to be $n=50$, based on sample sizes applied in similar studies published before. The statistical analyses were correct, so we found corrections and enlarging the group were not necessary.

Group A consisted of 50 patients treated with decompression of the entrapped neural elements, enlargement of the intervertebral foramina through disc space elevation by use of ceramic corundum implants, and providing immediate motion segment stability supplemented without posterior instrumentation.

Group B consisted of 50 patients treated with decompression of neural structures by fenestration with facetectomy of inferior articular processes. Data with patient demographics are shown in Table 1. There was no statistical significance regarding age, BMI, and sex.

The corundum implants were designed at the Department of Orthopedic Surgery of the Center of Postgraduate Medical Education in Otwock in cooperation with the Glass and Ceramic Institute. The porosity of implants is similar to that of the mineral structure of the cancellous bone, and their resilience modules were also similar. The implant, after it fuses with bone, forms a resistant composite, well visible in X-ray images, as it does not undergo resorption. The bioceramic corundum implants are made of close-grained aluminium oxide Al_2O_3 and fired at $1730^{\circ}C$. Figure 1 presents corundum implants. Figure 2A and 2B show AP and lateral view of 3D-CT image of the lumbar spine 10 years after surgery. Porous corundum implants are visible in the L4-L5 interbody space.

Table 1. Group A patients who were treated surgically with the use of porous ceramic cylindric corundum implants. Group B patients treated with decompression by fenestration with facetectomy of inferior articular processes. The difference were not statistically significant.

	Age		BMI	
	Mean	SD	Mean	SD
Group A n=50	57.74	9.22	27.34	4.15
Group B n=50	51.28	12.08	28.84	3.64

Figure 1. Photograph of corundum implants.

Statistical analysis

The results were evaluated through 2-factor repeated measures analysis of variance. The between-subject factor was the type of surgical treatment, and the within-subject factor was the change of results following the treatment. Means in

particular experimental conditions were additionally contrasted through the t-test.

Results

Perioperative data were presented in Table 2. Differences between duration of operation, intraoperative blood loss, time to ambulation, and hospitalization were significantly different for $p < 0.05$ in favor for the decompression group. Post-operative drains were not used in either group.

All the patients were monitored by the operating surgeon at 6 weeks, 6 months, and 1 year after surgery, and then annually.

The subjective scale of disability as expressed by the patients, based on the Oswestry disability index, [9], the Rolland- Morris disability questionnaire [10], and the visual analogue scale (VAS 0–10), were used as the treatment effectiveness criteria. Functional scales were collected from the patients before surgery, 1-year after surgery, and ten years later.

Figure 2. (A, B) AP and lateral view of 3D – CT image of the lumbar spine. Porous corundum implants are visible in interbody space L4-L5. Ten years post-surgery.

Table 2. Perioperative parameters.

	Group A – corundum PLIF group		Group B – decompression group	
Length of operation (min)	82	(±11.4)*	41	(±3.2)
Intraoperative blood loss (ml)	205	(±30.7)*	110	(±25.1)
Time to ambulation (days)	5.5	(±1.7)*	3.2	(±1)
Days of hospitalization (days)	7.8	(±1.5)*	5.2	(±2.1)

* Differences were significantly significant for $p < 0.05$.

Figure 3. Flow chart of the inclusion process from the original study to the 10-year follow-up of functional disability.

Table 3. Functional outcomes and results of VAS scale, means and standard deviations.

	Preoperative				One year				10 years			
	Group A		Group B		Group A		Group B		Group A		Group B	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Oswestry in %	41.01	10.10	63.80*	12.63	14.3	9.00	18.36*	10.14	16.3	10.00	22.36*	11.18
Rolland-Morris	16.07	5.88	14.15	3.24	7.57	5.83	7.17	4.42	8.57	5.88	8.17	4.44
Vas	8.57	1.21	8.17	0.9	3.98	2.14	4.15	1.59	4.96	2.13	4.35	1.69

* Differences were significantly significant for $p < 0.01$.

Follow-up rate at the evaluation point at 1 year was 99 patients, and 93 at 10 years. It was impossible to get information from 3 patients belonging to group A (2 patients had died and 1 had changed address) and from 4 patients belonging to group B (all 4 had changed addresses) (Figure 3).

Before surgery

The Oswestry disability index prior to the treatment revealed serious disability (41.01% [±10.10]) for group A and full disability (63.80% [±12.63]) for group B; the difference was statistically significant, with $p < 0.01$.

The Rolland-Morris disability questionnaire revealed mean disability of 16.07% (±5.88) in group A and 14.15% (±3.24) in group B, but the difference was not statistically significant.

The visual analogue scale (VAS) revealed a mean pain level of 8.57 (±1.21) in group A and 8.17 (±0.9) in group B, but the difference was not statistically significant.

Follow-up after surgery

The Oswestry disability index revealed minimal disability at 1 year after surgery in group A, and moderate disability in group B. The difference between the groups was statistically

significant, with $p < 0.01$. Long-term results showed a slight insignificant increase of disability, but the difference between the groups was still statistically significant, with $p < 0.01$.

The Rolland-Morris disability questionnaire at 1 year after the operation revealed mean disability of 8.57% (± 5.88) and 7.57% (± 5.83) after 10 years in group A, and 7.17% (± 4.42) after 1 year and 8.17% (± 4.44) after 10 years in group B. This difference between the groups was not statistically significant.

The visual analogue scale (VAS) revealed a mean pain level of 3.98 (± 2.14) after 1 year and 4.96 (± 2.13) after 10 years in group A, and mean pain level of 4.15 (± 1.59) after 1 year and 4.35 (± 1.69) after 10 years in group B. This difference between the groups was not statistically significant (Table 3).

The slight insignificant increase of patient disability in ODI and RM scales as well as in VAS scale were probably connected with aging.

The analysis of variance of the Oswestry disability index revealed a significant impact of the within-subject factor ($F_{1,91} = 899.97$; $p < 0.001$). The improvement 10 years following the surgery evaluated by the Oswestry disability index between the groups was statistically important. Also, the interaction of factors was significant ($F_{1,91} = 50.126$; $p < 0.001$); therefore, the increase in patient health was greater.

The surgical treatment resulted in achieving minimal and moderate disability according to the Oswestry disability index in group A; therefore, the clinical result was good in 44 patients (95.7%). The result was unsatisfactory (disability was moderate) in 2 patients (4.3%).

The Oswestry disability index revealed that the decompression performed in patients of group B resulted in a good clinical result in 45 patients (95.7%). Like in group A, there were also 2 patients whose results were unsatisfactory.

In the case of the Rolland-Morris disability questionnaire, the within-subject factor played an important role ($F_{1,91} = 132.46$; $p < 0.001$), which shows that this questionnaire also revealed a decrease in patient disability. However, interaction of factors proved irrelevant here, and effectiveness of both methods with this questionnaire should be evaluated as being similar. The visual analogue scale (VAS) confirms the above-mentioned effects. A significant impact of the within-subject factor ($F_{1,91} = 476.97$; $p < 0.001$) was demonstrated, but there is no interaction between this factor and the method of treatment.

The following complications were observed in group A: 1 patient had malposition of the corundum, but did not require

reoperation. One patient in group A needed additional posterolateral fusion with autologous graft due to instability. In group B, during 10 years of observation, 3 patients had surgery on this same segment due to recurrence of symptoms. There were no cases with adjacent disc disease in the PLIF group. The hypothesis that fusion of a single segment of the spine causes increased motion that leads to disc prolapse was not observed in the examined group.

We observed adjacent segment lateral stenosis due to degenerative changes in intervertebral joints and ligamentum flavum thickening in:

- 4 patients (8.5%) from group A; they were re-operated at between 6 and 8 years after primary surgery, with a mean of 7.16 (± 0.63) years, and
- 6 patients (13.04%) from group B, who were re-operated on between 3 and 7 years after primary surgery, with a mean of 5.13 (± 1.27) years.

In both groups no patients were operated on due to disc extrusion during the follow-up period.

Discussion

Ceramic implants used in the PLIF surgical treatment have not been widely discussed in the English literature in the last 10 years.

Łukawski et al. reported the early treatment outcomes of PLIF with corundum implants evaluated according to the Oswestry disability index. In almost 80% of patients, the clinical result achieved was good or satisfactory [11].

These implants were supposed to be an alternative to metal implants, which are much more expensive. Also, the surgical treatment with the use of interbody metal implants is much more extensive, with the risk being much higher than in operations without the use of any implants [12–14].

Corundum implants discussed in this paper were used in 50 patients with clinical symptoms of single-level stenosis. It was assumed that the interbody fusion would ensure stability and eliminate the cause of the pain, while the reconstruction of the intervertebral space height would prevent or delay the development of secondary stenosis on the reconstructed level.

The long-term results in group A showed that patients treated by interbody fusion with the use of ceramic corundum implants have not exceeded the long-term results of treatment without the interbody fusion. Treatment by decompression was, however, less invasive. In this kind of treatment, no surgical difficulties related to the proper situating of implants occur.

Group B consisted of 50 patients treated by decompression only. The justification for this treatment was the conviction that degenerative changes in posterior facet joints and intervertebral discs in their natural process of development lead to a secondary stabilization of the motor segment. Additionally, the precise determination of the level of condition through clinical examination, as well as the removal of its cause (the compression on neural structures) in the course of the surgical treatment, is a well-documented course of action. During the decompression procedure, if the intervertebral joint is retained with a part of inferior articular process, the vertebral arches and processes, together with the anterior wall of the spinal canal and posterior longitudinal ligament, the neurological structure can be decompressed without causing instability on the operated level.

Results similar to ours were described by Fu et al. [15]. They evaluated short-term results of treatment of lumbar stenosis by 2 different methods of decompression: fenestration and laminectomy. They advised performing a surgery with minimal intervention because this makes the surgery less expensive.

In contrast, several studies reported opposite results. Watanabe et al. [16] reported that they used the PLIF procedure to implant 31 patients (33 segments), in combination with segmental pedicle screws, interbody cages, and autogenous local bone graft, achieving excellent clinical outcomes, and in their opinion it was a rational and useful surgical option for treatment of lumbar foraminal stenosis. Weiner et al. treated patients with severe stenotic changes by TLIF (transforaminal lumbar interbody fusion) and found that this technically demanding procedure could be performed with relatively few complications and offered excellent rates of arthrodesis [17]. A similar conclusion was reached in a register study of 9051 patients by Sigmundsson et al. They concluded that patients with predominant back pain undergoing decompression and fusion were more satisfied with their treatment at 1-year follow-up and had better outcome in terms of health-related quality of life than patients who underwent decompression only [4].

Promising results combining advantages of both methods – minimal approach and fusion – were reported by Perez-Cruces et al., was reported the short- and long-term outcomes from a large cohort (n=304) of patients undergoing minimally invasive transforaminal lumbar interbody fusion (MITLIF). Similar to our findings, the above-mentioned authors stated that the VAS scores decreased significantly (from 7.0 preoperatively to 3.5) and the Oswestry Disability Index scores declined from 43.1 preoperatively to 28.2 at mean 47-month follow-up. Moreover, the long-term benefits observed in this study included a reduced rate of adjacent segment disease requiring reoperation, while providing high rates of fusion and a low rate of complications [18].

The ideal and long-lasting surgical treatment of lumbar spinal stenosis with associated mild spinal deformity is still debated in the literature and reported results vary [5,6]. Anjarwalla et al. found that spinal canal decompression improves the functioning of the patients, and reduces back pain and lower limb pain. Patients report that their social life improves. Unfortunately, 5 years after the operation, patients deteriorate again [19].

Brodke et al. conducted a retrospective cohort analysis of 90 consecutive patients (mean age 70 years), with 5-year mean follow-up, treated for stenosis with associated deformity, using 3 different methods: interspinous process spacer (ISP) device placement, laminectomy alone, or laminectomy and short-segment fusion. The authors stated that there was a significantly higher rate of same-level recurrence in the ISP group (33.3%) than the laminectomy (8.3%) and laminectomy combined with fusion (0%) groups [5].

Deyo et al., in a retrospective cohort analysis including 99 084 patients who underwent surgery for spinal stenosis, used different methods: an the interspinous process spacer (ISP) device placement alone, laminectomy and spacer, decompression alone, or decompression with fusion, and reported the revision rates at 2 years to be 16.7% for the ISP, 8.5% for decompression alone, and 9.8% for lumbar fusion. [6]. Results of reoperation in decompression alone and in lumbar fusion were comparable at 2 years after surgery.

We have obtained similar results, with 8.5% reoperations in the fusion group, and 13.04% in the decompression group, but our observation period was much longer.

Another way to evaluate the benefits of performed surgery is measuring the level of patient pain, functioning, and disability. In our study, at 10-year follow-up, the results were still beneficial, and observed disability was minimal to moderate.

Japanese authors in a prospective study evaluated 70 patients in whom laminectomy with or without arthrodesis was performed by VAS scale. They found that the results of the surgery improved steadily for 6 months after the operation, and then remained stable for the next 5 years. In elderly patients, especially women, results were worse than those in young men and women [20]. Our results showed a decrease in pain level after surgery, from VAS 8.57 in the PLIF group and 8.17 in the decompression group, to 4 and 4.17 after 1 year, and slight increase to 4.96 and 4.35, respectively, after 10 years.

An important measure of the value of surgery was also the percentage of patients who return to work (RTW). Nguyen et al. analyzed long-term (10-year) results in 725 patients treated with arthrodesis compared to 725 controls who were randomly selected. They discovered that 26% of fusion cases had RTW,

while 67% of nonsurgical controls had RTW. Surgery was connected with a large percentage (27%) of re-operation. In 36% of patients, there were complications and a large increase in using opioid drugs when compared to the control group not treated surgically [21]. In this study, we did not analyze the rate of return to work, but most probably this problem is significant. A total of 75% of the patients operated on for lumbar spinal stenosis do not return to their preoperative work. Difficulties in returning to work and decreased quality of life are associated with female sex, lower education, hard physical work, and low income [1].

We should not forget about physiotherapy after lumbar spinal canal stenosis surgery. Exercises should constitute an integral

part of the medical treatment. It is a process which enables the fastest possible patient recovery and helps to achieve optimal activity in a way that is safest for the patient [22–24].

Conclusions

Long-term results evaluated according to the ODI, the Rolland-Morris disability questionnaire, and the VAS showed that both methods gave significant reduction in patient disability, which was maintained during the next 10 years. The less invasive fenestration procedure was only a little less favorable than surgical treatment of stenosis by both PLIF with corundum implants and decompression.

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