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Single level discectomy with and without disc prosthesis

A comparative study of 114 patients

Tayfun Çakır, MD[a,*], Mürteza Çakır, MD[b], Hilmi Önder Okay, MD[c], Coşkun Yolaş, MD[c], Osman Tanrıverdi, MD[d], Muhammed Ömeroğlu, MD[e], Yusuf Kemal Arslan, MD[f]

Abstract

Background: Low back and leg pain due to lumbar discal hernia (LDH) is an important health issue. Current evidences support surgery in carefully selected patients who have failed conservative treatment and do not exhibit any psychosocial overlay. However, as known, sometimes it may be still very difficult to normalize the life qualities of patients for long times. Now different surgical methods for LDH are in use with new technological materials. One of them is lumbar disc prosthesis. In this study, the radiological and clinical effects of using lumbar disc prosthesis were evaluated with comparing patients underwent simple lumbar microdsicectomy. The purpose of this study is to reveal whether inserting the disc prosthesis into the intervertebral distance after lumbar microdiscectomy is beneficial or not both radiologically and clinically.

Methods: A total of 114 patients were analyzed; the first cohort consisted of 57 patients who received a lumbar discectomy at a single level along with the implantation of a disc prosthesis and the second consisted of 57 patients only received a lumbar discectomy at a single level. These 2 groups were studied by comparing the disc space on the level of carried out operations with pain scales, foramen diameters of coming about related roots preoperatively and postoperatively at 3 years.

Results: One of the significant results of the implementation of the disc prosthesis is fulfilment of a healthy disc height again after microdiscectomy due to LDH. We concluded that fulfilment of a healthy disc height with lumbar disc prosthesis was clinically beneficial for patients underwent microdiscectomy.

Conclusions: Based on the results obtained in this study, it can be concluded that the implantation of a disc prosthesis in appropriate patients is more favorable regarding pain and spinal physiology when compared to simple microdiscectomy.

Abbreviations: CCI = Charlson comorbidity index, DDD = degenerative disc disease, IVD = intervertebral disc, LBP = low back pain, LDH = lumbar discal hernia, LTDR = lumbar total disc replacement, MRI = magnetic resonance imaging, MSU = Michigan State University, PEEK = polyaryletherketone, VAS = visual analog pain scale, VASbp = VAS back pain, VASlp = VAS leg pain.

Keywords: disc height, lumbar disc prosthesis, lumbar discectomy

1. Introduction

Low-back pain (LBP) is the principal cause of long-term disability worldwide with a point prevalence of 18% and a 1-year prevalence of 38%.[1] The most common source of LBP is intervertebral degeneration leading to degenerative disc disease (DDD) or lumbar disc herniation (LDH).[2] Usually following unsuccessful conservative treatments, patients with DDD or LDH may be recommended for surgery.[2] Unfortunately, sometimes we find it difficult to find the most useful surgical method for the patients with LDH. Certainly, lumbar total disc replacement (LTDR) is a proposed method for LDH possibly to prevent failed back surgery syndrome.[3] The concept of LTDR is to relieve the low back and leg pain by replacing a herniated intervertebral disc (IVD) with a synthetic prosthesis, which will mimic the range of motion of the innate IVD and thus restore its functional anatomy and biomechanics.[4] Until today, many devices have been proposed for this intention and positive feedback have been reported.[5] In our clinic NUBAC disc prosthesis (Fig. 1), constructed in a unique two-piece design of a polyaryletherketone (PEEK) biomaterial with an inner ball/socket articulation launched by Victrex in 1998 have been used as main device. In this study, 114 patients who had been operated with or without lumbar disc prosthesis were revealed. We aimed to report the 3-year clinical and radiological results of the NUBAC device by comparing with patients performed lumbar microdiscectomy.

2. Materials and methods

2.1. Data collection

Participants were formed from patients operated by 2 surgeons between 2010 and 2014 years in Neurosurgical Clinic of

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[a] Department of Neurosurgery, Erzincan University Medical Faculty, [b] Department of Neurosurgery, Atatürk University Medical Faculty, [c] Department of Neurosurgery, Erzurum Training and Research Hospital, Erzurum, [d] Department of Neurosurgery, Mazhar Osman Mental Health and Nervous Diseases Hospital, Istanbul, [e] Department of Neurosurgery, Toyotasa Emergency Hospital, Sakarya, [f] Department of Biostatistics, Erzincan University Medical Faculty, Erzincan, Turkey.

[*] Correspondence: Tayfun Çakır, Erzincan University Medical Faculty Mengücekgazi Training and Research Hospital, Erzincan, Turkey (e-mail: tayfuncakir198375@gmail.com).

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Figure 1. İmage of the NUBAC disc prosthesis constructed in a unique two-piece design of a polyaryletherketone (PEEK) biomaterial with an inner ball/socket articulation launched by Victrex. PEEK = polyaryletherketone.

Erzurum Regional Training and Research Hospital. At the first stage, 75 patients who underwent single level LTDR surgery, data were collected preoperatively, but at the end of 3 years 57 patients could be reached and they were included the study. Also the 57 patients who underwent simple level microdiscectomy and met the same inclusion criteria with the study group were included to create a control group. Exclusion criteria were previous disc surgery, spondylolisthesis, spinal stenosis, concomitant disc herniation on the opposite side at the same segment or at a different segment, Pfirrmann grade 4–5 disc degeneration.

Tenam forms were received from all patients and ethics committee approval of this study was taken from Erzurum Regional Training and Research Hospital.

2.2. Participants

The average age of the patients of the first group was 39.1 years (range from 33 to 45), 33 of the patients were males and 24 of them were females. Around 31 of the patients were operated from L4-5 disc herniation and 26 of them were operated from L5-S1. For the control as we named second group; the average age of the patients was 38.4 years (range from 31 to 45), 32 of the patients were males and 25 were females. About 30 of the patients were operated from L4-5 disc herniation and 27 of them were operated from L5-S1 as seen in Table 1.

First of all, for all of the patients Charlson Comorbidity Index (CCI) scores were determined preoperatively and the possible difference between the 2 groups was analyzed statistically. In addition to this, all patients responded to a questionnaire containing a 10-point visual analog pain scale (VAS) for leg and low back pain preoperatively and postoperatively after followed-up for a period of 3 years (±2 months).

Table 1

Patient characteristics.

	Group 1 n (%)	Group 2 n (%)	*P*
Sex			
Males	33 (57,9)	32 (56,1)	.850
Females	24 (42,1)	25 (43,9)	
Operation level			
L4-L5	31 (54,4)	30 (52,6)	.851
L5-S1	26 (45,6)	27 (47,4)	
MSU classification grade			
2	34 (59,6)	38 (66,7)	.437
3	23 (40.4)	19 (33.3)	

MSU = Michigan State University.

2.3. Radiological assessment

Plain standing anteroposterior and lateral lumbar spine x-ray were taken preoperatively and postoperatively about 3 years (±2 months). Magnetic resonance imaging (MRI) scans were performed for all patients in both 2 groups preoperatively within the preceding 8 weeks at most on a 1.5-Tesla scanner (Magnetom Aera, SIEMENS) and all original images were input into advantage workstation to achieve sagittal, coronal and axial images.

Foramen diameters of coming about related roots and disc heights from the middle of the superior border to the middle of the inferior border of the disc distance with the inclusion of both endplates were measured on the lateral plain x-rays as seen in Figure 2A and B. In our radiology department, all patients were x-rayed at the same position and at the same distance as usual. Also all radiographs were independently evaluated by one certified neurosurgeon and one radiologist who were blinded to the classification groups of this study.

2.4. Statistical analysis

The results were presented for categorical variables as numbers and percentages, for continuous variables as mean (minimum–maximum). Comparison of the categorical variables between groups was done using Chi-square or Fisher exact test. The normality of the continuous variables was confirmed by using the Shapiro–Wilk test of normality. Operation type and time effects on disc heights and foramen diameters were evaluated by repeated measures ANOVA. While the main/interaction effect was significant, Bonferroni correction was applied for multiple comparisons. According to operation groups, the values of disc heights and diameter over time were presented with profile plot. Linear regression analysis was used to assess the changes in the value of VAS leg pain (VASlp) and VAS back pain (VASbp) according to changes in disc height and foramen diameter. The statistical level of significance for all tests was considered 0.05. Statistical analysis was performed using the IBM SPSS ver. 19 (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp.).

2.5. Surgical technique

This surgical technique includes the following main steps: patient positioning in a prone position; 3–4 cm long median skin incision; subperiosteal exposure of the interlaminar space; laminectomy (involving both the inferior edge of the hemilamina above and the superior edge of the hemilamina below), resection up to the medial one third of the medial facet bone and partial flavectomy; nerve root retraction; removal of eventual free disc fragments and annular cutting to obtain a small window through the annulus; total nucleus pulposus evacuation; annular window dilatation; (only for the patients in the second group) trial spacer implant sizing; (only for the patients in the second group) implant insertion into the disc cavity. We aimed mostly at placing the prosthetic disc material in a central position and we inserted trial devices to confirm the proper disc prothesis size that should be implanted.

3. Results

Residual disabling pain despite 6 to 8 weeks' full medical treatment and predominance of radicular pain was essential

criterion for surgery for all patients and leg pain in every case outweighed the intensity of back pain. No asymmetric leg pain was seen any patients. All patients had either size-2 or size-3 herniations according to the Michigan State University (MSU). Classification and all patients reported discreet radicular sensory patterns suggesting one or 2 dermatome levels, most often L5 or S1.

There was no significantly disparity between the 2 groups about average CCI score (respectively 0.92–0.90). ($P = .40$). There were no significant differences in sex ($P = .850$), operation segment ($P = .851$) and MSU grade ($P = .437$) between the groups (Table 1).

3.1. Comparison of radiological findings

The mean disc height of the patients in the first group preoperatively was 8.99 (range from 6.52 to 11.2) and postoperatively 3rd year it was 8.59 (range from 6.55 to 10.81. In the second group preoperatively it decreased from 9.43 mm (range from 6.01 to 10.90) to 6.61 mm (range from 5.07 to 9.0).

As shown in Figure 3, the decrease of the disc height (preop–postop) in group 2 were greater than group 1 and both were statistically significant ($P < .05$). That is, the disc heights of the patients in the first group were protected better with the use of disc prosthesis.

The foramen diameter average value decreased from 16.44 to 16.20 mm in the first group whereas it was decreased from 17.11 to 14.04 mm in the second group.

As shown in Figure 4, the decrease in foramen diameter in group 2 were greater than group 1 and both were statistically significant ($P < .05$). That is, the foramen diameter of the patients in the first group was protected better with the use of disc prosthesis.

3.2. Comparison of clinical findings

When VAS of all patients were evaluated it was seem that in the first group VASlp decreased from 8 (range from 10 to 7) to 3.02 (range from 4 to 1) and in the second group it decreased from 7.6 (range from 10 to 8) to 3.91 (range from 5 to 1). The decrease in VASlp values in both groups was statistically significant. When multiple regression analyses were made it was found that 1 mm decrease in the disc height caused 0.026 unit increase in the value of VASlp and 1 mm decrease in the foramen diameter caused 0.077 unit increase in the value of VASlp.

Additionally VASbp was measured for all patients preoperatively and 3rd year postoperatively. In the first group VASbp decreased from 7.65 (range from 10 to 8) to 2.02 (range from 3 to 1) and it was decreased from 7.0 (range from 10 to 8) to 4.23 (range from 6 to 1) in the second group. The decrease in VASbp

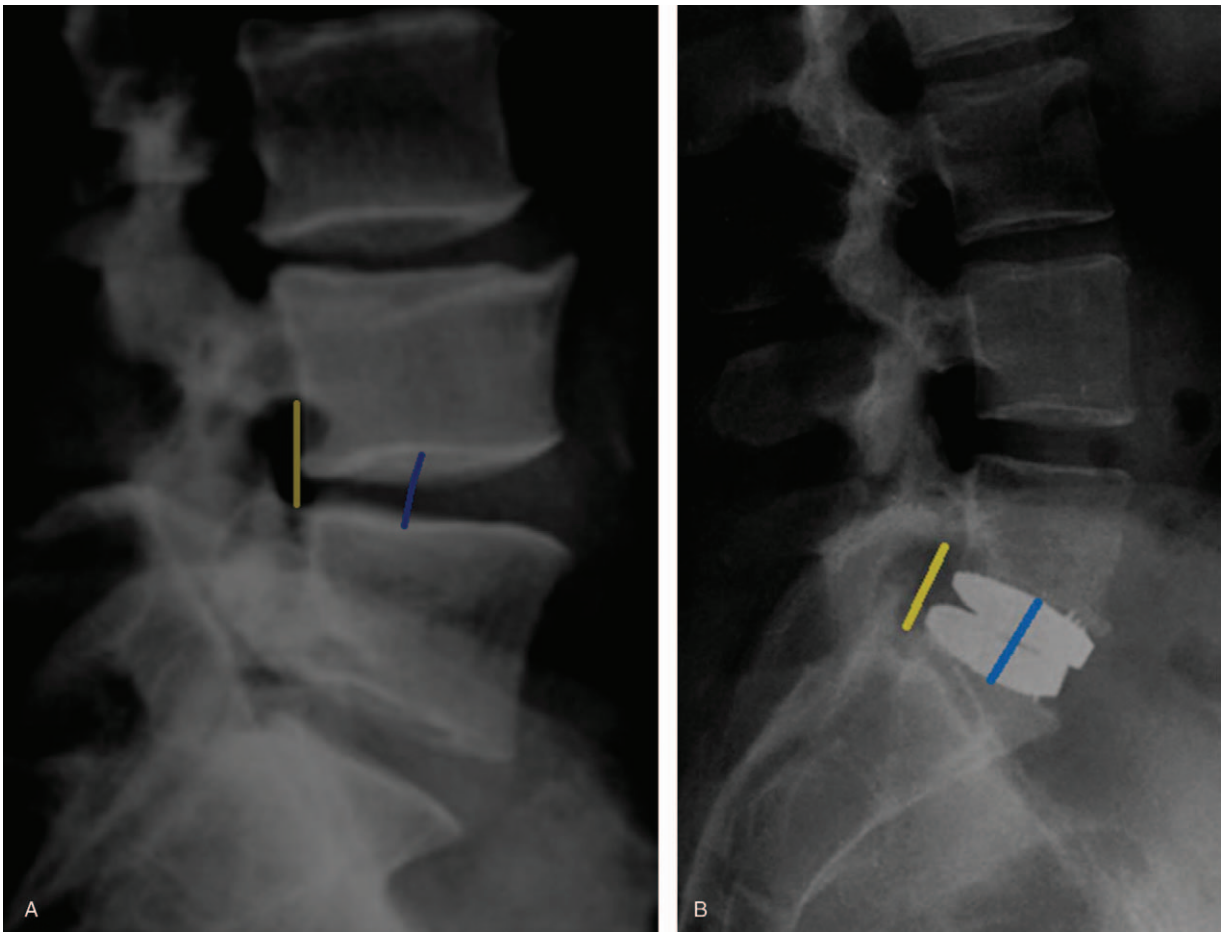

Figure 2. (A) Measurement of the disc height and foramen diameter at an x-ray image of a patient who underwent simple discectomy. Blue line shows where the disk height is measured and yellow line shows where the foramen diameter is measured. (B) Measurement of the disc height and foramen diameter at an x-ray image of a patient who underwent lumbar total disc replacement (LTDR). Blue line shows where the disk height is measured and yellow line shows where the foramen diameter is measured. LTDR = lumbar total disc replacement.

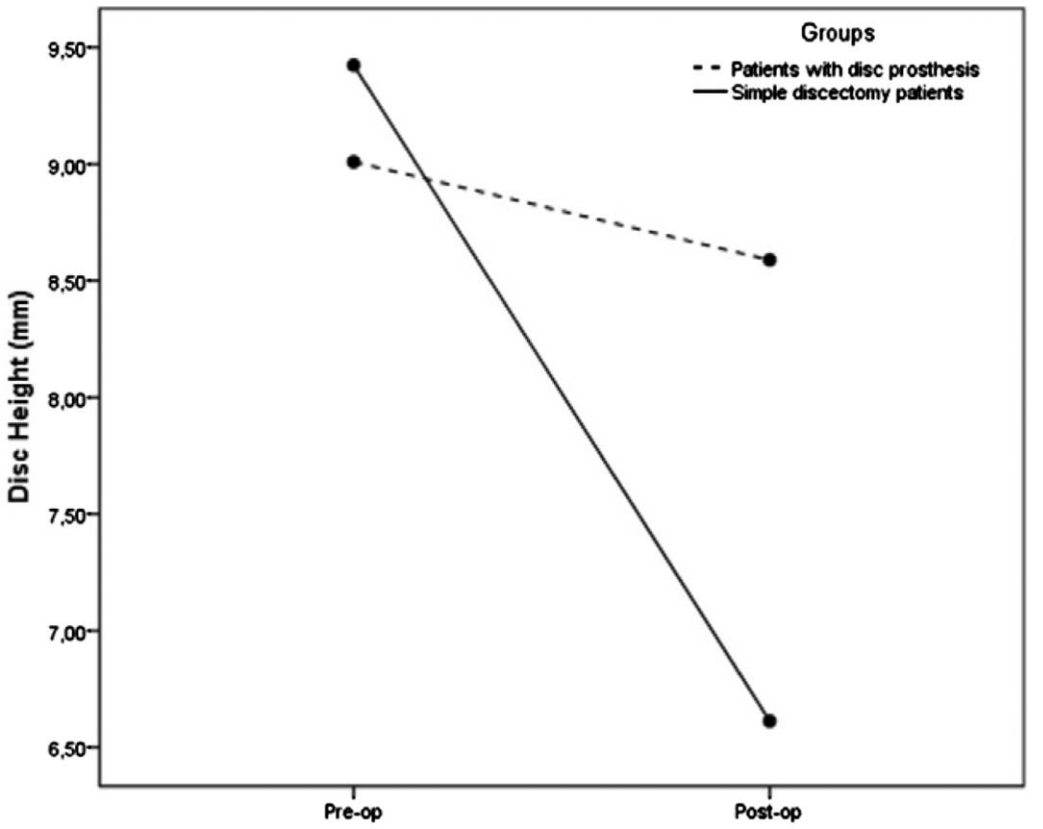

Figure 3. Comparison of disc heights.

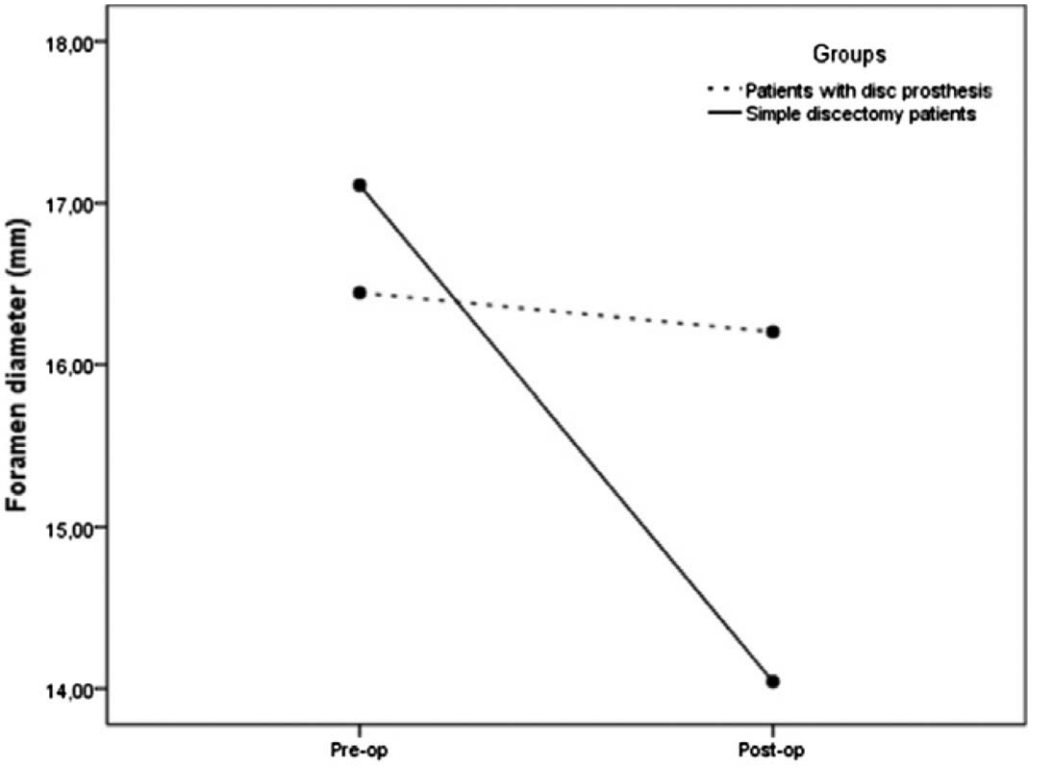

Figure 4. Comparison of foramen diameters.

values in both groups was statistically significant but when multiple regression analyses were made, it was found that 1 mm decrease in the disc height caused 0.12 unit increase in the value of VASbp and 1 mm decrease in the foramen diameter caused 0.57 unit increase in the value of VASbp.

No recurrence was seen in the first group but in three patients (5.2%) the disc prosthesis was displaced without breaking and they had to be surgically removed. Additionally; in the second group recurrence discal hernia was observed in 8 patients (14%) and 3 of them (5.2%) were operated again.

4. Discussion

Without any doubt microdiscectomy currently constitutes the standard treatment for LDH.[6] But unending or newly formed low back or leg pain after lumbar microdiscectomy is a frustrating situation for both patients and spinal surgeons. As we talk about a large number of patients in the society, it is important to understand the cause of unending or newly formed low back or leg pain after lumbar microdiscectomy. Previous studies have shown that by restoring the disc height, tension on the posterior facet joints may be reduced, degenerative cascade in adjacent vertebral segments may be avoided and thus patients can be treated with more physiologic method.[7] Posterior surgical approach was used in our all patients. There was no requirement of disrupting of facet joint structure in our cases. And any vertebral instability have not already been observed at the end of 3 years. When we examine the previous publications, it is seen that posterior surgical approach have been used seamlessly.[8]

In this context, it becomes meaningful to consider LTDR as a procedure that provides normalization of the disc height.[9] McGirt et al[10] showed in their work that an 18% loss of disc height was observed 3 months after lomber discectomy and 26% loss after 2 years. Also Yorimitsu et al[11] observed a significant reduction in disc heights in a series of 72 patients who had undergone standard lumbar microdiscectomy. In 2007, Karatoprak et al[12] conducted a study of 34 patients with lumbar disc prosthesis and found that disc heights increased from 4.6 to 12.1 mm after an average period of 2 years. It looks like an excellent result on a 2-year follow-up.[12] It was seen in our study that, disc height loss and chiefly foramen diameter decreasing led to increasing low back and leg pain of the patients. Previous studies have shown similar clinical outcomes, as sample; Tropiano et al[13] reported patient satisfaction after disc prosthesis as 87% and rate of return to daily activities and previous job was 72% in his study with minimum one year follow-up. Also Bertagnoli and Kumar published short-term outcomes of 104 patients treated with Prodisc II in their prospective study and they reported 41% mean reduction of pain according to VAS scores, 24% mean reduction in Oswestry Disability Index and 96% patient satisfaction; rate of return to work was found to be 50% in 2 years follow-up.[14]

Besides all of these, usage of disc prosthesis can reduce the need for second surgery. In our study, in simple discectomy group a recurrence rate of 14% was observed, and this finding was consistent with the literature.[15] In our study, no recurrence was seen in the patient group with a lumbar disc prosthesis. In 3 patients, the disc prostheses were displaced in the first year after surgery. Only one of these 3 patients was admitted to the hospital with complains of radiculopathic pain, the others were seemed with LBP. All of these 3 patients had no neurological problems but the disc prostheses had to be surgically removed. The complication rate in our study was observed to be 5.2%. This value was interpreted as a value close to the results in the literature.[16] In their study, Tropiano et al[13] found no recurrence after a follow-up of one year in their patients with lumbar disc prosthesis, with a complication rate of 9% and a reoperation rate of 6%. They reported no mechanical failure of the implants or loosening. Tropiano defended that total disc replacement has the potential to replace fusion as the gold standard surgical treatment of DDD.[13]

In the light of the obtained results, it can be interpreted that the use of lumbar disc prosthesis is more effective in reducing the pain compared to performing discectomy alone. Many biomechanical studies have shown that normal mechanical functions of a disc can be restored due to disc prosthesis. Upcoming data on long-term outcome, implant durability and possible very late complications will determine the future of lumbar disc replacement surgery. By restoring the disc height, the artificial disc would increase the exiting foraminal height and prevent compression on the exiting nerve roots. We think that it is important to offer an alternative to surgical treatment of LDH which is quite common in society. Based on the results obtained in this study, it can be concluded that using total disc prosthesis in appropriate patients is more favorable regarding the pain and spinal physiology when compared to simple discectomy. At the moment, we are of the opinion that although it might take more effort to optimize the design and reduce costs and risks, disc replacement with disc prosthesis will be the future of spine care.

Author contributions

Data curation: Hilmi Önder Okay, Muhammed Ömeroğlu, Yusuf Kemal Arslan.
Formal analysis: Yusuf Kemal Arslan.
Methodology: Mürteza Çakır, Hilmi Önder Okay, Osman Tanrıverdi.
Project administration: Hilmi Önder Okay, Coşkun Yolaş.
Resources: Mürteza Çakır, Coşkun Yolaş.
Writing – original draft: Osman Tanrıverdi, Muhammed Ömeroğlu, Yusuf Kemal Arslan.
Writing – review & editing: Tayfun Çakır.

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