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2-YEAR RESULTS OF NUBAC™ DISC ARTHROPLASTY SYSTEM IMPLANTED FOR THE TREATMENT OF LUMBAR DİSC HERNIATION

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ABSTRACT

Purpose: To assess the 2 year results of lumbar disc herniation patients treated with NUBAC™ disc arthroplasty system.

Methods: 10 patients (<45 years), with large disc herniation, otherwise relatively well preserved disc who presents with recalcitrant leg pain refractory to conservative treatment were included to the study. NUBAC™ disc arthroplasty was performed via standard posterior approach. Per-operative and 2 year follow-up scores (VAS, ODI) were obtained. Plain X-rays were performed on the postoperative first day and 6, 12 and 24 months after surgery while MRI and dynamic X-Rays were performed on the postoperative 24 months. Furthermore, adjacent disc degeneration were evaluated on the T2-weighted midsagittal MR images according to Pfirrmann classification.

Results: 5 of 10 patients were male. Average patient age at the time of surgery was 32,3. Statistically significant difference was observed in the radicular pain group ($p<0.05$) while the difference was not significant in terms of low back pain ($p>0.05$) 2 years after surgery. Lumbar MRI's performed 2 years after surgery did not show any additional degenerative changes on the adjacent discs. Any vascular and/or neurological complication did not occur.

Conclusion: NUBAC™ is a promising device which may help surgeons to reduce pain while restoring motion and protect adjacent discs.

Key words: Disc herniaton, surgical treatment, NUBAC™ disc arthroplasty.

Level of Evidence: Retrospective clinical study, Level III.

INTRODUCTION

Lumbar disc herniation is the most common cause of sciatica. Ninety percent of acute attacks settle down with conservative treatment methods. The usual indication for surgery is to provide rapid relief of pain and disability while the absolute indications are progressive muscle weakness and impaired sphincter function. Micro-discectomy is the treatment of choice in the surgical treatment of lumbar disc herniation [11,12]. However, it is well known that significant proportion (5-15 %) of patients who undergo micro-discectomy may develop recurrent disc herniation or symptomatic low back pain due to progressive degenerative process Figure-1 [10].

Since decrease in the disc space height and dehydration are commonly seen after discectomy operations, partial disc replacement in the post-discectomy setting offers the theoretical benefit of slowing future degenerative changes by maintaining disc space height and normal motion [4,11].

Figure-1. NUBAC™ is a 2-piece articulated PEEK intradiskal arthroplasty device.

Nucleus replacement devices are a heterogeneous group of implants

composed of diverse biomaterials with varying biomechanical properties. NUBAC is a 2-piece mechanical nucleus. It is the first poly-ether-ether-ketone (PEEK) on PEEK articulated intradiscal arthroplasty device [10].

In this study, we report 2 year outcomes of lumbar disc herniation patients treated with NUBAC disc arthroplasty system.

MATERIALS AND METHODS

Patient Characteristics

From October 2007 to November 2011, a total of 13 patients underwent nucleus disc arthroplasty at the level L4-5 with the NUBAC disc arthroplasty system in our clinic. Ten patients with 2-year follow-up were included to the study.

Patient Selection

The inclusion criteria for disc arthroplasty were young patients (<45 years), with large disc herniation, otherwise relatively well preserved disc who presents with recalcitrant leg pain refractory to conservative treatment. Exclusion criteria were recurrent disc herniation, spondylolisthesis, spinal stenosis and disc height <5 mm (Figure-2).

Surgical Procedure

Standard posterior surgical approach was used in all cases. After the patient was placed in prone position, a 4-5 cm verticomedian skin incision was performed on the level L4-5. After the subperiosteal dissection, lamina and facet joint were exposed. The laminatomy, partial medial facetectomy and flavectomy were performed in traditional manner. After the removal of nucleus pulposus, L5 root was retracted medially and the proper NUBAC implant was inserted. The extent of the medial facetectomy was defined by the size of the NUBAC implant.

Clinical Assessment

Before surgery, all patients responded to a 10 point Visual Analog Scale (VAS) for radicular and axial low back pain. Functional outcomes were measured using the Oswestry Disability Index (ODI) scores. Peroperative and 2-year follow-up scores were obtained (Table -1). Disc heights were measured on the lateral plain X-rays. Plain X-rays were performed on the postoperative first day and 6, 12 and 24 months after surgery while magnetic resonance imaging (MRI) and dynamic X-Rays were performed on the postoperative 24 months (Figure-3).

Furthermore, adjacent disk degeneration were evaluated on the T2-weighted midsagittal MR images according to Pfirrmann classification (Figure-4) [15].

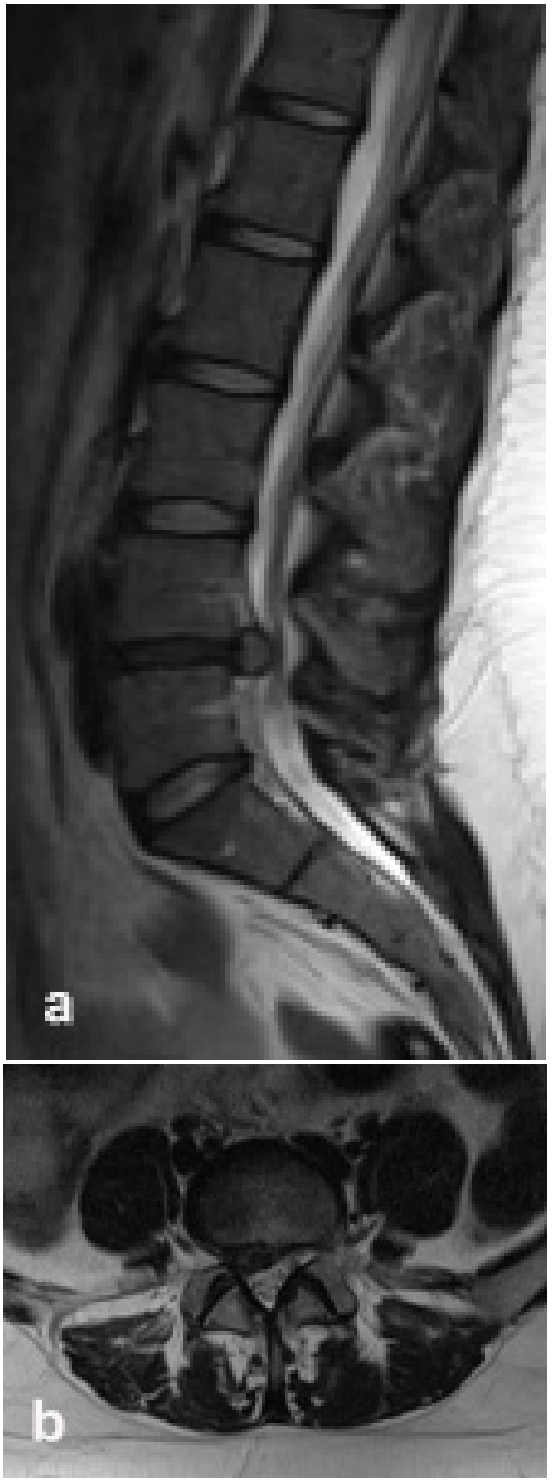

Figure-2. Sagittal **(a)** Axial **(b)** T2 weighted MR images showing L4-5 right paracentral disk herniation compressing the right L5 nerve root. Please note that the other disks are quite healthy.

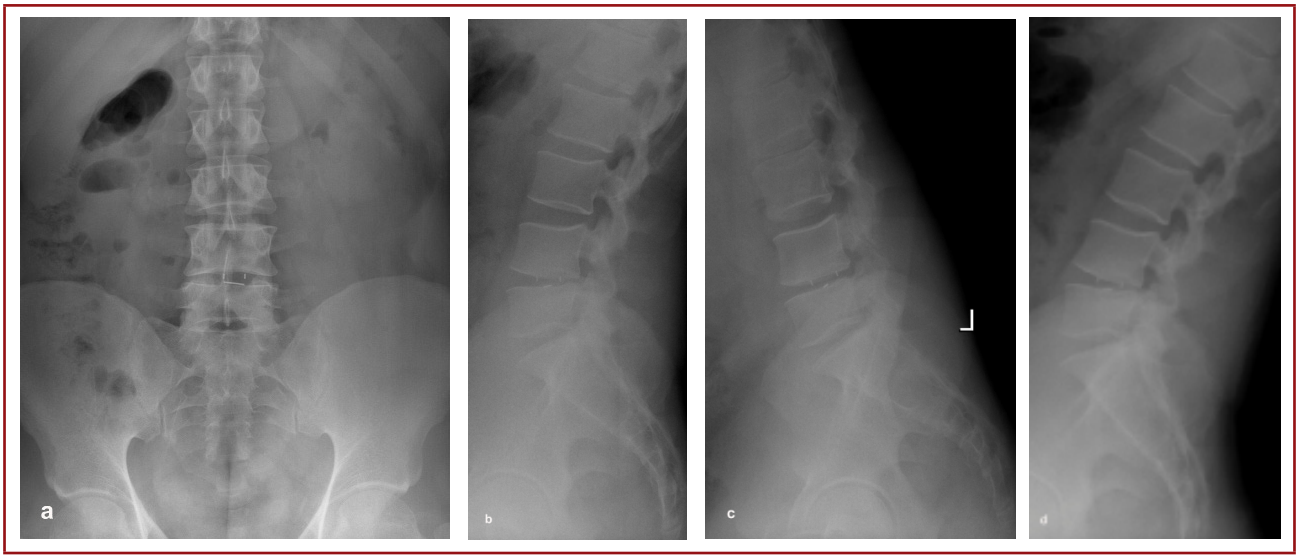

Figure-3. AP **(a)** Lateral **(b)** Hyperflexion **(c)** and Hyperextension **(d)** X-Ray images showing the position and regular functioning of NUBAC device 2 years after surgery.

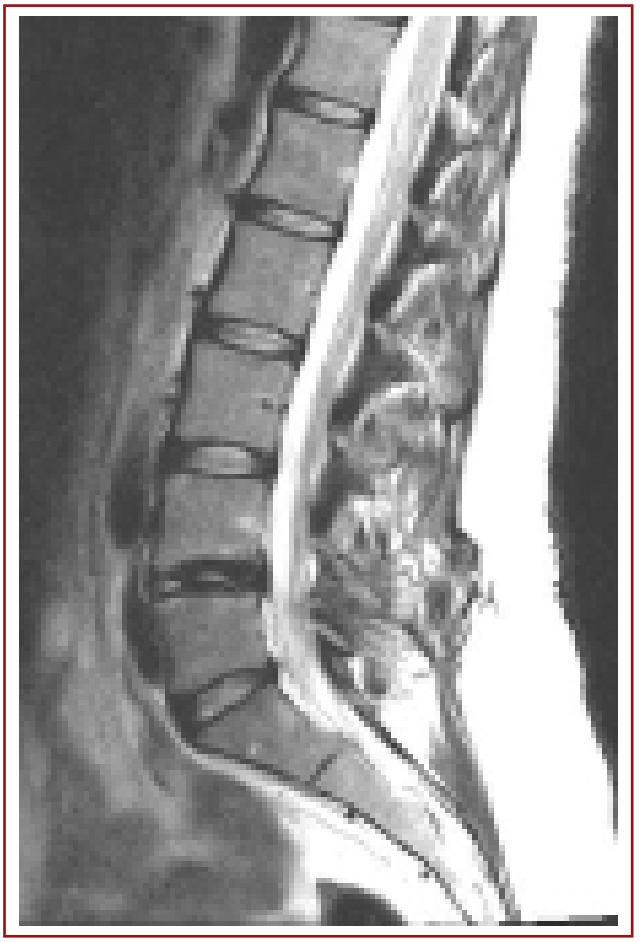

Figure-4. Sagittal T2 weighted MR image revealing the still healthy adjacent disks 2 years after surgery.

Statistical Analysis

All the data collected throughout the clinical study were evaluated using SPSS 11.5 statistical software for Windows. Non-parametric analysis were performed using Wilcoxon signed rank test. A P value less than 0.05 was considered statistically significant.

RESULTS

5 of 10 patients were male. Average patient age at the time of surgery was 32,3 (ranging from 23 to 45). The median preoperative VAS score for axial LBP was 1 (minimum: 0, maximum: 3) which was increased to 1.5 (minimum:0, maximum:4) 2 years after surgery. This difference was not statistically significant ($p>0.05$). However, statistically significant difference was observed in the radicular pain group ($p<0.05$). The median preoperative VAS value for radicular pain was nine (minimum: 8, maximum: 10) which was decreased to 1 (minimum: 0, maximum: 4) 2 years postoperatively. The median preoperative ODI score of 10 % was increased to 14 %, 2 years after surgery. This difference was not statistically significant ($p>0.05$). Lumbar MRI's performed 2 years after surgery did not show any additional degenerative changes on the adjacent discs (Table-2).

No vascular and/or neurological complication did occur. 2 patients who were describing increased low back pain after NUBAC surgery had benefit of facet joint injection.

Table-1. Patient Demographics

Case	Age	Sex	Level	VAS(Preop) LBP/Leg Pain	VAS(Postop*) LBP/Leg pain	ODI(preop)	ODI(Postop*)
1	45	M	L4-5	1/10	0/0	10	8
2	33	F	L4-5	1/8	4/1	12	42
3	23	M	L4-5	3/9	0/4	20	14
4	30	M	L4-5	1/10	3/1	10	34
5	29	M	L4-5	0/9	2/0	10	34
6	27	F	L4-5	0/10	0/2	8	12
7	28	F	L4-5	1/8	1/1	10	10
8	32	F	L4-5	2/9	2/1	10	14
9	43	M	L4-5	1/8	2/1	10	14
10	33	F	L4-5	2/10	1/3	12	8

* 2 years, LBP: Low back pain, VAS: Visual Analog Scale, ODI: Oswestry Disability Index

Table-2. Magnetic resonance classification of adjacent intervertebral disks (Pfirrmann classification)

Case	Age	Sex	Preoperative L3-4/L5-S1	Postoperative* L3-4/L5-S1
1	45	M	2/3	2/3
2	33	F	2/4	2/4
3	23	M	2/3	2/3
4	30	M	2/3	2/3
5	29	M	3/2	3/2
6	27	F	2/2	2/2
7	28	F	2/1	2/1
8	32	F	1/2	1/2
9	43	M	3/3	3/3
10	33	F	2/2	2/2

* 2 year

DISCUSSION

The development of spine arthroplasty technology may help surgeons to relieve pain while restoring the motion and protect adjacent levels [4,10]. Arthroplasty can be divided into 2 subtitles as total disc replacement (TDR) and partial disc replacement (PDR) or nucleus replacement [10]. In TDR, entire disc including the anulus and endplates are replaced with a prosthesis while only degenerated nucleus is replaced in PDR [10].

There are several advantages of having a nucleus prosthesis over a total disc prosthesis. PDR is a minimally invasive procedure that involves limited exposure and annulotomy[4,10]. Surgeons have multiple approach options such as anterior retroperitoneal, lateral and posterior approaches [3,6]. However, risk of retropulsion or migration and subsidence are the two main problems related with the PDR [10,14].

There are two well-defined indications of PDR [4,10]. The first indication is to prevent recurrent disc herniation or progression of degeneration in selected young patients who have undergone discectomy. The second indication is to try to diminish mechanical low back pain due to early or moderate degenerative disc disease [10]. The main objective of having a nucleus prosthesis is to restore the disc anatomy and functions [4].

Bertagnoli et al published their experiences with the PDN® prosthetic disc nucleus device in 2002 [5]. They implanted this device in degenerative disc disease patients and indicated a surgical success rate of 88 %, coupled with a marked reduction in back pain and an increase in disc height. In 2003, Korge et al published 2 year clinical results of 5 patients implanted a coiling spiral as nucleus prosthesis for the treatment of lumbar disc herniation [13]. They reported promising results about the implant. Ahrens et al published 2-year efficacy and safety results from 2 prospective, non-randomized multicenter European studies of DASCOR® disc artroplasty device in Spine in 2009 [1]. They concluded that DASCOR device may be a safe and effective less-invasive surgical option for patients with DDD.

Functionally, nucleus replacement devices can be divided into 2 broad classifications as elastomeric and mechanical [10]. Elastomeric devices can also be further subdivided into hydrogel and nonhydrogel replacements. Mechanical devices can be subdivided into 1 and 2 piece designs. These devices are composed of various materials including metal, pyrolytic carbon and PEEK [10].

NUBAC™ (Pioneer Surgical Technology, USA) is a nucleus replacement device for use in the treatment of low back pain due to DDD [3,7-8]. It is unique between nucleus replacement devices since it incorporates articulation in its design [10]. It is composed of 2 pieces from PEEK and uses a ball and socket articulation for motion. It has been CE approved since 2005 and has been implanted in over minimum 250 patients worldwide [7-8,10].

Balsano et al reported the 2-year clinical outcome of 22 patients who underwent nucleus disc arthroplasty with NUBAC® device [3]. They concluded that NUBAC could be considered as a viable option for the treatment of low back pain due to degenerative disc disease. Similarly, Alpizar-Aguirre et al from Mexico reported clinical and radiological improvement after NUBAC implantation for the treatment of DDD [2]. A clinical trial (NCT00931515) evaluating the safety and effectiveness of NUBAC disc arthroplasty finished in 2012 [16].

In this study, we decided to use NUBAC device because of its unique articulated technology manufactured from PEEK. PEEK is commonly used in spine surgery because of its excellent mechanical strength, stability, biocompatibility and radiolucency [8]. Furthermore, Brown et al showed that wearing rates were relatively low and consistent thus suggesting long term durability [8]. Brown et al also compared the NUBAC device with the total joint arthroplasty implants in terms of particle load. And they found reduced particle load in NUBAC device group that diminish the risk to elicit an inflammatory response [7].

Since our patient population had a diagnosis of disc herniation at the level L4-5, we used the posterior approach to evacuate the disc and to place the NUBAC device. We performed the same surgical steps with Bucciero et al [9]. In contrary to Bucciero et al, we had to perform a wide hemilaminotomy and resection of one third or one half of the facet joint in order to achieve minimum nerve root retraction during NUBAC placement. Especially in small stature patients, it was not easy to place the NUBAC device properly with performing limited medial facetectomy. Surgeons should evacuate the nucleus pulposus entirely in order to rotate the implant properly and easily. Otherwise, implant does not rotate and stays in oblique position.

The extent of facetectomy is directly proportional with the postoperative LBP. In our series 2 of 4 patients experiencing increased LBP after surgery had benefit from facet joint injection. When we examined their surgery records and radiological images retrospectively, we had realized that their facetectomy was more than average.

According to our experience, we suggest that posterior route is more suitable for patients who have wide L4 lamina and/or suffer from L5-S1 disc herniations. If NUBAC device implantation is planned for the treatment of DDD, anterior retroperitoneal or anterolateral transpsoatic approach (ALPA) would be better to use in order to avoid paravertebral muscle denervation, facet joint violation and related pain [6].

As mentioned above, there is significant risk (5 %-15 %) of recurrent disc herniation after microdiscectomy alone [10]. In our patient group with NUBAC device, we did not encounter any recurrent disc herniation. The most important complications of nucleus devices placed via posterior route are device migration and subsidence [10,14]. We did not observe any device migration/retropulsion or subsidence in our study. Disc heights of the operated level did not decrease after surgery and during the 2 years of follow-up.

Adjacent segment degeneration is one of the pitfalls of fusion surgeries. Zigler et al reported that 5 years after index surgery adjacent segment degeneration was observed in 26,8 % of fusion patients [17-18]. Furthermore, this value was found 3 times greater than the TDR patients. In this study 2 years after surgery, patients underwent lumbar MRI to observe adjacent segment degeneration. Adjacent discs (L3-4/L5-S1) were graded according to Pfirmann classification. Any significant difference was not found in terms of adjacent segment degeneration.

In our patient population, leg pain diminished dramatically after NUBAC disc arthroplasty. The median preoperative VAS value for radicular pain was 9 (minimum:8, maximum:10) which was decreased to 1 (minimum:0, maximum:4) 2 years postoperatively. This difference was found statistically significant ($p<0.05$). It is hard to attribute this decrease to NUBAC implantation directly. This decrease seems mostly secondary to discectomy and root decompression. When we look at the ODI and VAS scores for low back pain, an increase was found between the preoperative and postoperative values. But this increase was not statistically significant ($p>0.05$). We blame facet joint violation for the responsible of this increased LBP after surgery.

Our study is unique since this is the first NUBAC study that is carried out in a homogenous, pure disc herniation group at the level L4-5. The disadvantage of our study is the limited number of patients with short follow-up time. To make a more precise, evidence based suggestion to perform NUBAC disc arthroplasty, a prospective, multicenter, randomized, controlled clinical trial with a long follow up time is needed. 190

Nucleus replacement systems are promising devices which may help surgeons to alleviate pain while restoring motion and protect adjacent discs. Indications and surgical techniques should be individualized according to benefit to risk and benefit to cost ratio.

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