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ORIGINAL ARTICLE

# Nucleus disc arthroplasty with the NUBAC$^{TM}$ device: 2-year clinical experience

**M. Balsano · A. Zachos · A. Ruggiu · F. Barca · P. Tranquilli-Leali · C. Doria**

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**Abstract** Low back pain (LBP) due to degenerative disc disease (DDD) is a common condition that can be treated along a continuum of care: from conservative therapies to several surgical choices. Nucleus arthroplasty is an emerging technology that could potentially fill part of the gap in the spine continuum of care. The introduction of recent technologies that allow the replacement of the degenerated disc nucleus using prosthetic devices may be considered an additional therapeutic tool that can be used by the surgeon in selected cases of LBP due to DDD. Nucleus arthroplasties are designed to treat early stages of DDD, which are one of the most common spinal disorders in the population under 65 years of age. NUBAC$^{TM}$ is the first articulating nucleus disc prosthesis, designed to optimally respect the lumbar anatomy, kinematics, and biomechanics, constructed in unique two-piece manufactured from polyetheretherketone (PEEK) with an inner ball/socket articulation. The optimal indications for NUBAC$^{TM}$ implantation are: disc height >5 mm, degenerative disc changes at an early stage (Pfirmann 2, 3), single level affection, integrity of posterior facet joints, lack of local anatomical contraindication, failure of conservative treatment for at least 6 months. From December 2006 to January 2009, a total of 39 patients underwent nucleus disc arthroplasty with NUBAC$^{TM}$ device. 22 cases have 2-year follow up. There have been no major intra-operative or post-operative vascular or neurological complications in this series. The data showed that there were significant decreases in both Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI) after the procedure, with a meaningful improvement of symptoms in all patients. Although preliminary, the initial results are encouraging. The absence of any major intra-operative and post-operative complications supports the design rationale of the NUBAC$^{TM}$, being less invasive comparing to total disc replacement (TDA) and with a low rate of surgical risk. The effectiveness of data as seen in 2-year follow-up on both VAS and ODI have also suggested that the NUBAC$^{TM}$ could be considered a viable treatment option for patients with LBP caused by DDD.

**Keywords** Lumbar spine · Back pain · Degenerative disc disease · Spinal arthroplasty · Nucleus arthroplasty

## Introduction

Degenerative disc disease (DDD) and its associated symptoms have traditionally been treated with spinal fusion where the affected vertebrae are immobilized with mechanical fasteners or cages [1–3]. Although this approach stabilizes the affected segments and provides pain relief, it is not without complications. Spinal fusion results in a decreased range of motion and may lead to a degenerative cascade in adjacent vertebral segments as these are addressed to compensate the immobilized section of the spine [4–6]. To avoid this and to treat patients leaving its physiologic motion, there have been many efforts to replace the disc with various kinds of devices.

M. Balsano
Orthopaedic and Vertebral Unit, Regional Department of Spinal Surgery, ULSS 4, Schio, Vicenza, Italy

A. Zachos · A. Ruggiu · F. Barca · P. Tranquilli-Leali · C. Doria
Orthopaedic Department, University of Sassari, Sassari, Italy

C. Doria (✉)
Via Pietro Satta Branca 18, 07100 Sassari, Italy
e-mail: reemad@tiscali.it

Currently there are two features of disc prosthesis: total disc device and nucleus disc device [7–11]. In contrast to total disc replacement, nucleus disc prosthesis preserves the existing structures, which include the annulus, endplates and ligaments [12–14].

Several designs of nucleus disc devices are now under development, and clinical trials are going on.

NUBAC™ is the first articulating nucleus disc prosthesis constructed in a unique two-piece design of a polyetheretherketone (PEEK) with an inner ball/socket articulation. This device's peculiarity provides a large contact area designed to distribute the load, reduce the contact stress and, subsequently, mitigate the risk of subsidence. PEEK is one of the best bearing material for articulating spine devices with well-established biocompatibility and biodurability [7, 8]. Since many patients with DDD are in their 30 and 40 years of age, it is extremely important to use materials with exceptional durability and wear resistance. The purpose of this study is to report the 2-year clinical results of the NUBAC™ device and thereby to evaluate the efficacy of the implant in patients with chronic low back pain (LBP) caused by DDD.

## Materials and methods

From December 2006 to January 2009, a total of 39 patients underwent nucleus disc arthroplasty with the NUBAC™ device in two different Orthopaedic Units (Schio and Sassari, Italy). There were 15 men and 24 women. Average patient age at the time of surgery was 38.5 ± 6.3 (range 32–45) years. The inclusion criteria were DDD manifested by morphologic changes (internal disc derangement, disc herniation) and clinical manifestations (back pain with or without leg pain) refractory to conservative therapy. All patients showed degeneration of the affected disc level on magnetic resonance imaging (MRI) with a residual disc height >5 mm. (Table 1). All patients had chronic back pain and radicular pain due to disc degeneration. In 11 cases, a concomitant disc herniation was present. Provocative discography was reserved only in two cases of multiple DDD to identify the level responsible for the pain.

22 cases in this series have 2-year follow-up.

Exclusion criteria were previous disc surgery, spondylolisthesis, spinal stenosis, moderate to severe osteoporosis, disc height <5 mm, Schmorl nodule.

Before surgery, all patients responded to a questionnaire containing a 10-point Visual Analogue Pain Scale (VAS) for radicular and LBP. Oswestry Disability Index (ODI) was performed for neurological assessment, activity, and functional status. The questionnaire was repeated at 6-week, 3, 6, 12 months, and 2-year postoperative. Plain

**Table 1** Profile of patients

| Case no. | Age/sex | Diagnosis | Level | Pfirmann classification |
|---|---|---|---|---|
| 1 | 35/F | DDD | L4/L5 | 2 |
| 2 | 32/F | DDH | L5/S1 | 3 |
| 3 | 38/F | DDD | L5/S1 | 2 |
| 4 | 40/M | DDD | L4/L5 | 3 |
| 5 | 42/M | DDD | L5/S1 | 2 |
| 6 | 38/F | DDD | L5/S1 | 3 |
| 7 | 36/F | DDD-DH | L5/S1 | 2 |
| 8 | 42/F | DDD | L4/L5 | 2 |
| 9 | 45/M | DDD | L4/L5 | 2 |
| 10 | 37/M | DDD | L5/S1 | 3 |
| 11 | F | DDD | L4/L5 | 3 |
| 12 | F | DDD-DH | L5/S1 | 2 |
| 13 | F | DDD | L5/S1 | 3 |
| 14 | M | DDD-DH | L4/L5 | 2 |
| 15 | F | DDD | L4/L5 | 3 |
| 16 | F | DDD-DH | L5/S1 | 3 |
| 17 | M | DDD | L5/S1 | 2 |
| 18 | F | DDD-DH | L4/L5 | 3 |
| 19 | F | DDD | L4/L5 | 3 |
| 20 | M | DDD | L4/L5 | 3 |
| 21 | F | DDD | L4/L5 | 2 |
| 22 | M | DDD | L5/S1 | 3 |
| 23 | F | DDD-DH | L4/L5 | 3 |
| 24 | M | DDD | L4/L5 | 2 |
| 25 | F | DDD-DH | L4/L5 | 2 |
| 26 | F | DDD | L4/L5 | 3 |
| 27 | M | DDD | L5/S1 | 2 |
| 28 | F | DDD | L4/L5 | 2 |
| 29 | M | DDD | L5/S1 | 3 |
| 30 | F | DDD | L4/L5 | 2 |
| 31 | M | DDD | L4/L5 | 3 |
| 32 | F | DDD | L4/L5 | 2 |
| 33 | F | DDD-DH | L5/S1 | 2 |
| 34 | F | DDD | L4/L5 | 3 |
| 35 | F | DDD-DH | L5/S1 | 2 |
| 36 | M | DDD-DH | L4/L5 | 3 |
| 37 | F | DDD | L5/S1 | 2 |
| 38 | M | DDD | L5/S1 | 3 |
| 39 | F | DDD-DH | L4/L5 | 2 |

*DDD* degenerative disc disease, *DH* disc herniation

X-rays and computed tomography (CT) scans were taken immediately after surgery and after 6 months (Fig. 1). An independent reviewer examined the X-rays and CT scans. Disc heights were measured on the lateral plain X-rays. Posterior surgical approach was used in 30 patients to implant NUBAC™ prosthesis, whereas in the remaining 9 patients was used an extreme lateral approach by a

retroperitoneal transpsoas via to anterior column. The levels treated by posterior approach were L5-S1 in 17 cases and L4-L5 in 13 cases. Extreme lateral approach was reserved to remaining 9 cases of DDD without disc herniation that affected the L4-L5 level. In the posterior approach, the patient is placed in a prone position, and a short paramedian skin incision is performed in the longitudinal direction. Fascia and muscle tissue are incised and retracted. The laminotomy and flavectomy are done in the traditional manner. After an annulotomy of 6 mm, the nucleus pulposus is carefully removed, the neural root is gently pushed aside and the proper NUBAC$^{TM}$ device is inserted.

In the extreme lateral approach, the patient is positioned in a direct lateral position and secured with tapes just below the iliac crest, over the thoracic region, from the iliac crest to knee and to the operative frame. Using lateral fluoroscopy, the disc space is localized by crossing two K-Wires over the pathological level and centering them over the indicated disc space. A mark on the skin is made at the intersection of the K-Wires to serve as the location of the skin incision for the operative corridor (direct lateral incision). The retroperitoneal space is accessed through posterolateral incision with blunt scissor and finger dissection. Once the psoas muscle is located, the index finger is swept up to the inside abdominal wall, underneath the direct lateral skin mark to ensure a safe pathway between the abdominal wall and the psoas muscle. An incision is made at this location and the initial dilator connected to EMG monitoring (NeuroVision, NuVasive Inc. San Diego, CA) is introduced. The finger is used to guide the initial Dilator safely past the peritoneum, down to the surface of the psoas muscle. The large NeuroVision Dynamic Stimulation Clip is attached to the proximal end of the initial Dilator, and the system is activated in Detection mode. As the Dilator is advanced through the psoas, NeuroVision's dynamically stimulated discrete EMG guidance is used to identify and avoid the nerves of the lumbar plexus. After the initial dilator is on the disc, a lateral radiograph confirms that the dilator is approximately centered on and parallel with the disc. A K-Wire is introduced approximately halfway into the disc space to verify the position. Subsequent dilation and muscle-splitting retraction are used to establish the operative corridor. A small transverse annulotomy is performed instead of creating a large opening in the annulus. A careful nucleotomy is performed and an effort is made to respect the end plates, so as to create enough space for the nucleus disc prosthesis. After discectomy, serial annular dilators are used to dilate the annulotomy, and trial devices are inserted to confirm the proper NUBAC$^{TM}$ size that should be implanted (Fig. 1). The disc prosthesis is introduced into the disc space and, in the posterior approach, is rotated in a transverse direction using a dedicated implant inserter, whereas in the extreme lateral approach the insertion of prosthesis is direct.

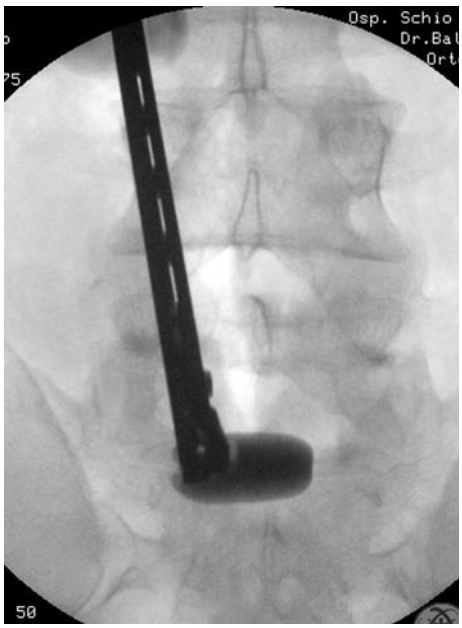


**Fig. 1** Intraoperative X-ray control during positioning of NUBAC$^{TM}$ trial into the disc space L5-S1

## Results

There have been no major intra-operative or post-operative vascular or neurological complications in this series. The data showed that there were significant decreases in both VAS and ODI after the NUBAC$^{TM}$ procedure. The average pre-operative VAS was 71, which was decreased to 43, 30, 22, 18, and 14 at 6-weeks, 3, 6, 12 months, and 2-year post-operatively, respectively (Fig. 2). The average ODI was decreased from 58% pre-operatively to 34, 23, 20, 18, and 14 at 6-weeks, 3, 6, 12 months and 2-year post-operatively, respectively. These initial results are very encouraging. The absence of any major intra-operative and post-operative vascular and neurological complications supports the design rationale of the NUBAC$^{TM}$ being less invasive and of less surgical risk. The initial effectiveness data as seen in the significant improvements on both VAS and ODI have also suggested that the NUBAC$^{TM}$ could be a viable treatment option for patients with low-back pain caused by DDD (Figs. 3, 4).

## Discussion

Given that the intervertebral disc bears some of the highest loads in the human body and is mainly avascular, it is not

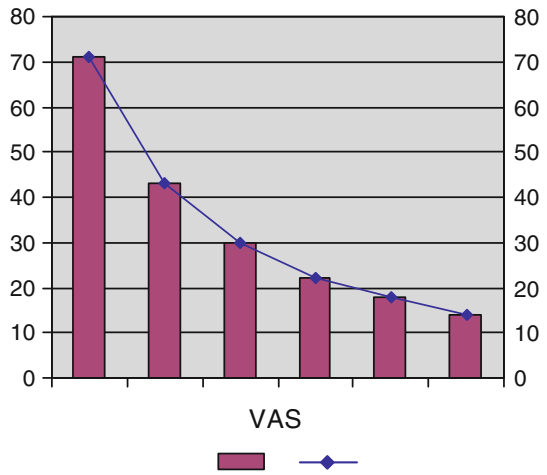


**Fig. 2** VAS results at the baseline, 6 weeks, 3, 6, 12, and 24 months post-operatively

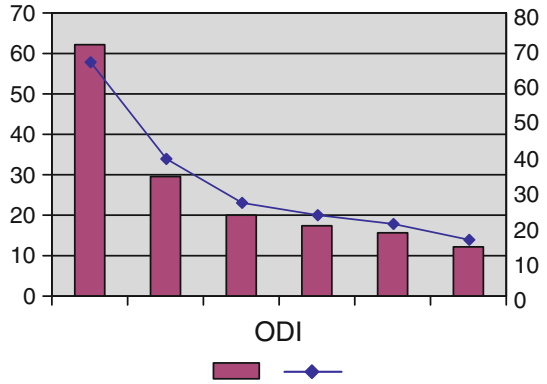


**Fig. 3** ODI results at the baseline, 6 weeks, 3, 6, 12, and 24 months post-operatively

surprising that DDD is a common phenomenon in middle age and a universal condition of the inescapable consequences of aging [15]. The vast majority of patients achieve acceptable results without surgery [16]. Small percentage of patients, however, does not respond to non-surgical modalities; in this, chronically disabled patient population surgery may be beneficial. DDD and its associated symptoms have traditionally been treated with spinal fusion. This technique results in a decreased range of motion and may lead to a degenerative cascade in adjacent vertebral segments [1, 17–20]. To avoid this and to treat patients with more physiologic method, there have been many efforts to replace the intervertebral disc. Nucleus arthroplasty is designed to treat early stage of DDD, which is one of the most common spine disorders in the population of middle age. This new technology should have properties of both restoration of disc height and maintaining the mobility of the segment. The nucleus arthroplasty had some advantages including the following: (1) the annulus, ligaments, and endplates are preserved; (2) the

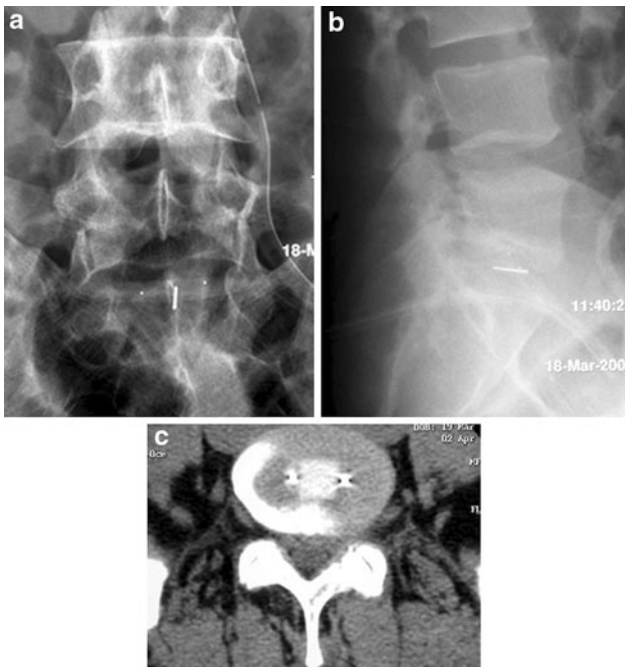


**Fig. 4** Plain radiographs on anteroposterior (**a**) and lateral (**b**) view show correct positioning of NUBAC prosthesis at L5-S1 level. CT scan (**c**) in axial view show the desired positioning of the implant inside the disc

procedure is less invasive, and (3) the implant technique is more familiar to spine surgeons [7–9, 19, 21, 22]. The NUBAC™ disc arthroplasty incorporates a two-piece ball-and-socket design that articulates within the disc space and provides load sharing and an even stress distribution in any position with low risk of implant expulsion. PEEK demonstrated exceptional biocompatibility and biodurability with minimal wear debris compared with other disc arthroplasty materials. Extreme lateral approach, when possible, allows access to the intervertebral disc with minimal disturbance to posterior structures, the bony elements of the spine are not compromised and there is no risk of damage to the dura and associated nerve tissue [10, 23].

## Conclusion

For long time, fusion was considered as the gold standard of surgical intervention, but concerns about the loss of function of the motion segment and the stress to the adjacent levels as well as clinical results have assured the acceptance of disc arthroplasty as the treatment option. The disc arthroplasty system aims at restoration of function and NUBAC™ Disc Arthroplasty System is a newly developed device that is intended to treat patients at an early phase by restoring function, while protecting levels and relief of pain. The NUBAC™ device was effective in patients with

DDD who had chronic back pain with or without leg pain. Nucleus arthroplasty has merit because it can treat both back and leg pain in a much less invasive way than fusion surgery. But long-term data are still necessary to determine the efficacy of the NUBAC$^{TM}$ device in the treating DDD without negative influence on the adjacent motion segments. Our study at 2 years also shows that the clinical outcome of NUBAC$^{TM}$ prosthesis is excellent. But this retrospective report has been limited by a small number of patients. However, our opinion suggests that NUBAC$^{TM}$ arthroplasty is a reasonable alternative to the fusion and total disc replacement.

**Conflict of interest** None.

## References


1. Kuslich SD, Ulstrom CL, Griffith SL, Ahern JW, Dowdle JD (1998) The Bagby and Kuslich method of lumbar interbody fusion. History, techniques, and 2-year follow-up results of a United States prospective, multicenter trial. Spine 23:1267–1279
2. Lehman TR, Spratt KF, Tozzi JE (1987) Long-term follow-up of lower lumbar fusion patients. Spine 12:97–104
3. Lemaire JP, Skalli W, Lavaste F (1997) Intervertebral disc prosthesis. Results and prospects for the year 2000. Clin Orthop 337:64–76
4. Enker P, Steffee AD (1997) Total disc replacement. In: Bridwell KH, DeWald RL (eds) The textbook of spinal surgery, 2nd edn. Lippincott-Raven, Philadelphia, pp 2275–2288
5. Hsu KY, Zucherman J, White A, Reynolds J, Goldwaite N (1988) Deterioration of motion segments adjacent to lumbar spine fusions. Trans N Am Spine Soc 12:605–606
6. Rahm MD, Hall BH (1996) Adjacent-segment degeneration after lumbar fusion with instrumentation: a retrospective study. J Spinal Disord 9:392–400
7. Bao QB, Yuan HA (2002) New technologies in spine: nucleus replacement. Spine 27:1245–1247
8. Bao QB, Yuan HA (2002) Prosthetic disc replacement: the future? Clin Orthop 394:139–145
9. Bao QB, Songer M, Pimenta L, Werner D, Reyes-Sanchez A, Balsano M, Agrillo U, Coric D, Davenport K, Yuan H (2007) Nubac disc artyhroplasty: preclinical studies and preliminary safety and efficacy evaluations. SAS J 1:36–45
10. Bertagnoli R, Vazquez RJ (2003) The anterolateral transpsoatic approach (ALPA). A new technique for implanting prosthetic disc nucleus devices. J Spinal Disord 16:398–404
11. Hedman TP, Kostuik JP, Fernie GR, Hellier WG (1991) Design of an intervertebral disc prosthesis. Spine 16(Suppl 6):S256–S260
12. Enker P, Steffee A, Mcmillan C, Keppler L, Biscup R, Miller S (1993) Artificial disc replacement. Preliminary report with a 3-year minimum follow-up. Spine 18:1061–1070
13. Fernstrom U (1966) Arthroplasty with intercorporal endoprothesis in herniated disc and in painful disc. Acta Chir Scand (Suppl) 357:154–159
14. Kostuik JP (1997) Intervertebral disc replacement. In: Bridwell KH, DeWald RL (eds) The textbook of spinal surgery, 2nd edn. Lippincott-Raven, Philadelphia, pp 2257–2266
15. Rothman RH, Simeone FA, Bernini PM (1982) Lumbar disc disease. In: Rothman RH, Simeone FA (eds) The spine, 2nd edn. WB Saunders, Philadelphia, pp 508–645
16. Weinstein JN (ed) (1992) Clinical efficacy and outcome in the diagnosis and treatment of low back pain. Raven Press, New York
17. Lee CK (1988) Accelerated degeneration of the segment adjacent to a lumbar fusion. Spine 13:375–377
18. Ray CD (1997) Threaded titanium cages for lumbar interbody fusions. Spine 22:667–680
19. Lee CK, Langrana NA, Parsons JR, Zimmerman MC (1991) Development of a prosthetic intervertebral disc. Spine 16(Suppl 6):S253–S255
20. Nachemson AL (1992) Challenge of the artificial disc. In: Weinstein JN (ed) Clinical efficacy and outcome in the diagnosis and treatment of low back pain. Raven Press, New York
21. Ray CD, Schönmayr R, Kavanagh SA, Assell R (1999) Prosthetic disc nucleus implants. Riv Neuroradiol 12(Suppl 1):157–162
22. Schönmayr R, Busch C, Lotz C, Lotz-Metz G (1999) Prosthetic disc nucleus implants: the Wiesbaden feasibility study. 2 years follow-up in ten patients. Riv Neuroradiol 12(Suppl 1):163–170
23. Ozgur BM, Aryan HE, Pimenta L, Taylor WR (2006) Extreme lateral interbody fusion (XLIF): a novel surgical technique for anterior lumbar interbody fusion. Spine J 6:435–443