Hernia blocking system

Prospective multicenter cohort clinical investigation

The aim of this prospective multicenter cohort clinical investigation was to evaluate the performance and safety of a new hernia blocking system (HBS), implanted after a limited discectomy, for recurrent lumbar disc herniation prevention.

Prospective, multicenter (6 sites), cohort clinical investigation. Thirty patients with a postero-lateral disc herniation between L4-S1 and large annular defects (> 6 mm wide), who underwent a limited discectomy and were treated with a new HBS (DISC care, NEOS Surgery S.L.), were included.

Godino et al. presents details about the investigational device, its surgical technique, intraoperative parameters, and up to 6 months follow-up outcomes. The primary endpoint of the study was to assess the incidence of early symptomatic reherniation. In addition, disc height, leg and back pain (NRS 0-10), Oswestry Disability Index (ODI), quality of life (EQ-5D-5L) and device safety, were evaluated.

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Thirty patients (43.3% female, 41.7 ± 10.9 years) were implanted with the device under evaluation in a mean of 16 ± 9.6 min. Six months after surgery, no symptomatic reherniation was detected and disc height was maintained in all patients included. All patients had a significant reduction in leg pain (> 2 points in the NRS), 92.9% improved > 15 points in the ODI and 82.6% significantly improved their quality of life (≥ 12 points in EQ VAS score). No product-related serious adverse events nor reoperations occurred.

The implantation of an HBS is a feasible and safe procedure that prevents early disc herniation recurrence in patients at high risk of reherniation [1].

Strengths of the Study Innovative Focus: The study introduces a new hernia blocking system (HBS), addressing a critical need in spine surgery—preventing recurrent lumbar disc herniation in high-risk patients. This innovation holds promise for improving post-discectomy outcomes.

Study Design: The prospective, multicenter cohort design strengthens the reliability of the findings by incorporating diverse surgical teams and patient demographics across six institutions. Such an approach minimizes potential biases from single-center studies.

Clear Methodology: The inclusion criteria are well-defined, focusing on patients with large annular defects and specific levels of herniation (L4-S1). Additionally, the assessment endpoints are clinically relevant, including reherniation rates, pain (NRS), disability (ODI), and quality of life (EQ-5D-5L).

Safety and Efficacy: The absence of symptomatic reherniation and maintenance of disc height at six months are significant outcomes, especially given the known challenges of recurrent herniation in this patient cohort. The lack of product-related serious adverse events and reoperations further supports the safety of the HBS.

Quantitative Results: Improvements in leg pain (>2 points in NRS), disability (>15 points in ODI for

92.9% of patients), and quality of life (≥12 points in EQ VAS for 82.6% of patients) are clinically significant, offering robust support for the device's efficacy.

Weaknesses and Limitations Short Follow-Up Period: While the six-month follow-up provides early insights into the device's safety and efficacy, recurrent disc herniations often occur beyond this timeframe. Longer-term data are essential to confirm durability and sustained benefits.

Small Sample Size: The study includes only 30 patients, limiting the generalizability of its findings. A larger cohort would enhance statistical power and the reliability of conclusions.

Lack of Control Group: The absence of a control group undergoing standard discectomy without HBS implantation makes it challenging to attribute observed benefits solely to the device. Randomized controlled trials (RCTs) are necessary to establish causation.

Subjective Outcome Measures: While NRS, ODI, and EQ-5D-5L are validated tools, they are subjective and may be influenced by patient expectations or placebo effects. Objective functional outcomes or imaging-based metrics could supplement these measures.

Potential Conflicts of Interest: The involvement of NEOS Surgery S.L. in providing the device introduces a potential bias. Transparency about funding and potential conflicts is crucial, though not explicitly addressed in the abstract.

Future Directions Extended Follow-Up: Studies with follow-ups of 2–5 years are needed to evaluate the long-term efficacy and safety of the HBS, particularly in preventing delayed reherniations and preserving disc height.

Larger, Controlled Trials: Conducting RCTs comparing HBS implantation to standard discectomy or other augmentation methods (e.g., annular closure devices) will provide more definitive evidence of its benefits.

Economic Analysis: A cost-effectiveness analysis of the HBS compared to traditional methods would be valuable, given the potential implications for widespread adoption in clinical practice.

Broader Patient Inclusion: Expanding the study to include patients with different types of disc herniations or annular defect sizes may clarify the broader applicability of the device.

Conclusion This study offers promising early evidence supporting the safety and efficacy of the HBS in preventing early recurrent lumbar disc herniation. Despite its limitations, the research sets a strong foundation for further investigation and highlights the potential of this novel device to address a significant clinical challenge. However, longer follow-ups, larger sample sizes, and randomized controlled comparisons are imperative to confirm these findings and establish the HBS as a standard of care in spinal surgery.

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Godino O, Fernandez-Carballal C, Català I, Moreno Á, Rimbau JM, Alvarez-Galovich L, Roldan H. A new hernia blocking system to prevent recurrent lumbar disc herniation: surgical technique, intraoperative findings and six-months post-operative outcomes. Eur Spine J. 2024 Dec 8. doi: 10.1007/s00586-024-08595-x. Epub ahead of print. PMID: 39648196.