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Lumbar arthroplasty

Clinical performance of an elastomeric lumbar disc replacement: Minimum 12 months follow-up

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Abstract

Background: Elastomeric disc replacements have been developed to restore normal shock absorption and physiologic centers of rotation to the degenerated disc. The Physio-L Artificial Lumbar Disc is an elastomeric disc which uses a compliant polycarbonate-polyurethane core with enhanced endurance properties. The objective of this study was to evaluate the safety and efficacy of the Physio-L through a 12-month follow-up period in a prospective, nonrandomized clinical trial.

Methods: Twelve patients who met the inclusion/exclusion criteria were enrolled in the study. Eight patients received a single implant (L5-S1) and 4 received a 2-level implantation (L4-5 and L5-S1). Patients were assessed preoperatively and postoperatively at 6 weeks and 3, 6, and 12 months. Primary outcomes included the VAS, ODI, a radiographic analysis of implant condition, incidence of major complications, and reoperations. Secondary outcomes included SF-36, ROM at index and adjacent levels and disc height.

Results: All patients completed the 12-month follow-up evaluations. Through 12 months, the Physio-L devices have remained intact with no evidence of subsidence, migration, or expulsion. VAS low-back pain and ODI scores improved significantly at all follow-up periods compared to preoperative scores. The range of motion of 13.3° ± 5.5° at the index level was considered normal. Overall, patients were satisfied with an average score of 83.5 ± 26.8 mm. When comparing the device to other artificial discs, the current device showed a clinically relevant improvement in both ODI and VAS scores at all follow-up time points. Statistically significant improvements in both scores were observed at 12 months ($P < .05$).

Conclusion: The Physio-L is safe and efficacious, as demonstrated by improved pain relief and functional recovery without any implant failures, significant device related complications, or adverse incidents. The clinical results for VAS and ODI were superior to other marketed artificial lumbar discs such as the Charité and ProDisc-L at the same follow-up timeframes.

Keywords: Lumbar; Total disc replacement; Spinal arthroplasty; Prospective clinical trial

Artificial disc replacements (ADR) have been under development for over 20 years for use as motion preservation alternatives to fusion in the treatment of chronic disabling low back pain caused by degenerative disc disease (DDD). Current designs of spinal disc prostheses typically achieve their desired motion by having one surface slide relative to another in a similar manner to total hip and total knee prostheses.[1–6] These rigid sliding surfaces are constructed from metal, polymer, or ceramic with differing types of motion dependent on specific designs. It is clear, however, that many of these designs lack resistance to motion and the ability to provide shock absorption. In recent years, mounting concern has been registered in the literature concerning accelerated facet joint degeneration at the index level, an increased rate of adjacent level degeneration after ADR, and stress fractures of the pars or pedicle at the index levels. These untoward effects may be related to the nonphysiologic nature of the design of these disc prostheses.[7–10]

To overcome these concerns, the use of elastomeric disc prostheses has been proposed to mimic physiologic levels of shock absorption and flexural stiffness; however, an earlier elastomeric disc design using a polyolefin core was developed and examined in clinical trials but was eventually

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Fig. 1. Physio-L artificial lumbar disc.

abandoned due to material failure.[11,12] With the recent availability of better fatigue-resistant and bio-stable polymers, a new generation of elastomeric disc prostheses has been developed. The current study evaluates the safety and efficacy of a new generation disc replacement through the 12-month follow-up period.

Materials and methods

The disc prosthesis

The Physio-L (Nexgen Spine, Whippany, NJ) lumbar artificial disc uses a compliant polycarbonate polyurethane that is securely attached to 2 titanium endplates by injection molding the polymer through perforated plates. This provides a purely mechanical attachment that employs no adhesives. This design allows the restoration of the normal range of motion and function of a healthy disc to the involved level (Fig. 1). The domed endplates are manufactured from medical grade titanium alloy and are porous coated with titanium beads to promote bone in-growth and long-term prosthesis-bone interface stability.

Study design

A prospective, nonrandomized clinical trial was conducted on 12 patients at 2 clinical sites to evaluate the safety of the artificial lumbar disc. All surgeries were performed by 1 of 2 surgeons between March and August 2007. Patients presenting with low-back pain caused by degenerative disc disease (DDD) were enrolled in the study after failing to respond to nonoperative treatment for a minimum of 6 months. Degenerative disc disease at 1 or 2 levels between L3-S1 was confirmed by patient self-reporting of back pain, MRI, and discography. All patients reported in this group fit within defined inclusion/exclusion criteria (Table 1). Contraindications included active systemic infection or localized infection near the implant site, isolated radicular compression symptoms due to disc herniation, allergy or sensitivity to implant materials, osteoporosis, lumbar stenosis, facet joints arthritis, osteopenia, pars defects, instability and/or deformity. Patient evaluations occurred preoperatively (within 3 months of surgery) and postoperatively at 6 weeks and 3, 6, and 12 months. Patients will be followed subsequently at 24 months.

Patient demographics

Eleven patients were male and 1 was female, with an average age of 40.6 ± 8.4 years (range, 25–55) and an average BMI of 26.3 ± 3.5 (range, 20.9–31.6). Of these patients, 8 received a single implant (L5-S1 level) and 4 received a 2-level implantation (L4-5 and L5-S1) (Fig. 2). A total of 16 artificial discs were implanted. All patients returned for each follow-up visit up to 12 months.

Surgical technique

The patient was positioned in the supine position and underwent anterior disc removal through an anterior retroperitoneal exposure of the lumbo-sacral spine, which is similar to other artificial disc replacement surgeries. Endplate preparation was performed using contoured bone rasps to closely match the specific dome shape of the metal endplates. A keel cutter was used to cut the channels on vertebral endplates for the central keel without violating the anterior cortex. Following endplate preparation, the artificial disc was inserted as a single unit.

Clinical outcome measures

Patient self-assessment outcome measures included the oswestry disability index (ODI), the visual analog scale (VAS) for back pain, and the Short Form 36 (SF-36) Health Survey questionnaire. A 10-point decrease in ODI scores and 18-point decrease in VAS scores were considered a minimal, clinically important difference (MCID).[13] Mental and physical component summary scores (MCS and PCS, respectively) were calculated from the SF-36 Quality of Life questionnaires. A 5-point increase in SF-36 scores was considered a clinically significant improvement.[14] Additionally, work status was collected at all follow-up evaluations and patient satisfaction was collected at 6 months and 12 months.

Radiographic analysis

Radiographs were analyzed using an independent radiologist and QMA™ Software (Medical Metrics, Inc., Houston, TX) to evaluate flexion/extension range of motion, disc height, loosening, subsidence, migration, and expulsion.[15]

Single versus 2-level implantation

Eight patients received the artificial disc at a single L5-S1 level and 4 patients received a 2-level L4-S1 implantation. Patient self-assessment scores of VAS back pain and ODI were compared between these 2 groups.