



# Ozone-augmented percutaneous discectomy: A novel treatment option for refractory discogenic sciatica



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**AIM:** To assess the short and medium-term efficacy and safety of a novel, minimally invasive therapeutic option combining automated percutaneous lumbar discectomy, intradiscal ozone injection, and caudal epidural: ozone-augmented percutaneous discectomy (OPLD).

**MATERIALS AND METHODS:** One hundred and forty-seven patients with a clinical and radiological diagnosis of discogenic sciatica who were refractory to initial therapy were included. Fifty patients underwent OPLD whilst 97 underwent a further caudal epidural. Outcomes were evaluated using McNab's score, improvement in visual analogue score (VAS) pain score, and requirement for further intervention. Follow-up occurred at 1 and 6 months, and comparison was made between groups.

**RESULTS:** OPLD achieved successful outcomes in almost three-quarters of patients in the short and medium term. OPLD achieved superior outcomes at 1 and 6 months compared to caudal epidural. There was a reduced requirement for further intervention in the OPLD group. No significant complications occurred in either group.

**DISCUSSION:** OPLD is a safe and effective treatment for patients with refractory discogenic sciatica in the short and medium term. OPLD has the potential to offer an alternative second-line minimally invasive treatment option that could reduce the requirement for surgery in this patient cohort.

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## Introduction

Sciatica is defined as radicular leg pain localized to the dermatological distribution of a pathologically affected

nerve root, which may also be accompanied by neurological deficits such as weakness or paraesthesia.<sup>1</sup> Sciatica is a common condition with research implicating both mechanical and chemical factors in its pathogenesis. Ninety percent of cases of sciatica are associated with lumbar disc herniation usually occurring at the L4–5 or L5–S1 level.<sup>2</sup> Mechanical stress, biochemical changes within the disc and genetic factors all contribute to progressive lumbar disc disease.<sup>3–10</sup> Eventually the degenerative process can lead to

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disc herniation, nerve root compression and the inflammatory cascade, which propagates and maintains the symptoms of sciatica.<sup>10,11</sup>

The prognosis of sciatica in the acute setting is often favourable with the majority of patients responding well to conservative treatment regimens of physiotherapy, non-steroidal anti-inflammatory drugs (NSAIDs), and oral analgesia. However, approximately 10% of patients require further intervention, and it is this cohort of patients which present a therapeutic dilemma.<sup>12</sup>

Surgery can produce satisfactory results in a high proportion of patients in the short to medium term. However, long-term studies have reported variable benefits with a high proportion of patients describing persistent pain. It is also known that surgical discectomy can cause mechanical disruption to adjacent vertebral levels leading to increased risk of degenerative change in these locations over time.<sup>13–17</sup> In addition, lumbar discectomy is an expensive, invasive surgical procedure, which carries a complication rate of at least 3% including discitis or neurological disability.<sup>18–20</sup> Due to the limitations of surgical discectomy in this patient cohort, there has been much focus upon minimally invasive, outpatient-based treatment options for discogenic sciatica.

For decades, caudal epidural injection has been the first-line minimally invasive therapeutic option for patients who are refractory to conservative management; however, they are generally a temporizing measure prior to surgery rather than a curative treatment. The steroid component of caudal epidurals directly reduces local inflammation associated with disc herniation by inhibiting synthesis of pro-inflammatory mediators, whilst the local anaesthetic component causes temporary neural blockade interrupting nociceptive input and the self-sustaining pain cycle of discogenic sciatica.<sup>21,22</sup> Caudal epidural injections have been shown to produce good short-term but poorer longer-term results.<sup>23,24</sup>

More recently novel minimally invasive, outpatient-based therapies for discogenic sciatica have been developed, which aim to replicate the effect of surgical discectomy whilst minimizing complications, reducing patient recovery times, and lowering healthcare costs. Two of the most promising of these techniques are automated percutaneous lumbar discectomy (APLD) and intra-discal ozone injection.

APLD aims to reduce mechanical nerve root compression by aspirating a volume of the nucleus pulposus of the herniated intervertebral disc using a percutaneously placed suction cutting probe.<sup>25</sup>

Intradiscal ozone injection involves injection of ozone gas into the nucleus pulposus of the herniated disc leading to proteoglycan hydrolysis and subsequent partial fibrosis.<sup>26–29</sup> This leads to a reduction in disc volume and relief of mechanical nerve root compression. In addition, diffusion of ozone into the surrounding tissues has direct anti-inflammatory and analgesic effects, inhibiting synthesis of pro-inflammatory mediators such as prostaglandins and bradykinins.<sup>30</sup>

APLD and intra-discal ozone injection have demonstrated significant promise in the treatment of discogenic

sciatica when administered individually.<sup>31–33</sup> However, no prior study has attempted to assess a therapeutic option combining these modalities, which could utilize a multimodal approach to decompress the disc herniation whilst simultaneously reducing the associated cascade of inflammatory mediators.

The aim of the present study was to assess the short and medium-term efficacy and safety of a therapy combining the modalities of APLD, intra-discal ozone injection, and caudal epidural injection, a therapy termed ozone-augmented percutaneous lumbar discectomy (OPLD).

## Materials and methods

### Study design

This study was designed using an observational cohort methodology based on the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Ethical approval was granted by the local ethics committee.

Consecutive patients attending the minimally invasive back pain service at Cappagh National Orthopaedic Hospital over a 12 month period, whose symptoms were refractory to initial therapy, were included in the study. Inclusion criteria included mild to moderate contained lumbar disc herniation (occupying <40% of the spinal canal) with evidence of nerve root compression on MRI lumbar spine; discogenic sciatica in a dermatological distribution corresponding to the herniated lumbar disc; symptoms of sciatica ongoing for at least 6 months; non-response to initial management consisting of oral NSAIDs, physiotherapy, and caudal epidural injections; and age over 18 years.

Patients were excluded in cases of large lumbar disc herniation (occupying >40% of the spinal canal) or evidence of compression of the cauda equina; significant structural deformity of spine (e.g., spondylolisthesis, scoliosis, acute vertebral body fracture); history of prior lumbar spine surgery; acute illness; pregnancy; and injury litigation.

The patients' demographic, clinical, and radiological characteristics were recorded. Diagnosis of lumbar disc herniation was confirmed after review of the patient's MRI by two experienced musculoskeletal radiologists. Diagnosis of discogenic sciatica was confirmed after clinical examination by a consultant orthopaedic surgeon.

As this was a primary safety and efficacy study, ethical approval for patient randomization was not permitted. After discussion of risks and benefits of each treatment option, patients were offered a choice between OPLD or caudal epidural injection alone and were permitted up to a week to make their decision.

The primary outcome measure was the McNab clinical outcome score (McNab score, [Table 1](#)). Secondary outcome measures were improvement in visual analogue pain score for sciatica (VAS sciatica score, with 0 indicating no pain and 10 indicating worst possible pain) after therapy and requirement to receive further interventional therapy (either minimally invasive or surgical). Each patient completed the VAS sciatica score prior to their procedure as a baseline

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