



Canadian Journal of Health Technologies

April 2023 Volume 3 Issue 4

CADTH Horizon Scan

# Low-Level Laser Treatment for Lower Back Pain

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**ISSN:** 2563-6596

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**Funding:** CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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## Key Messages

- The CADTH Horizon Scanning Service identifies emerging health technologies that may be of potential interest to health care decision-makers in Canada.
- Chronic pain, including chronic low back pain, challenges many aspects of people's lives, including social, physical, mental, and professional. Approximately 80% of adults will be affected by chronic lower back pain at least once in their lifetime and seek out multiple treatment options, including drug treatments, psychological treatments, and physical therapies.
- This Horizon Scan summarizes available information regarding an emerging technology, the Erchonia FX 635 low-level laser system, for the treatment of chronic low back pain.

## Introduction

### The Erchonia FX 635 Laser: Low-Level Laser Therapy for Back Pain

As an alternative to pharmacotherapy, the Erchonia FX 635 is a noninvasive and painless option for treating lower back pain. The low-level laser therapy, also referred to as cold laser therapy, is the first to be cleared by the FDA for treating lower back pain.

## How It Works

The Erchonia FX 635 laser system emits light energy at 635 nm to provide relief for chronic and musculoskeletal pain.<sup>1</sup> It has 2 arms that can be adjusted by the health care provider to align with the painful area, such as the lower back.<sup>1</sup> Low-level laser therapy, also referred to as cold laser therapy, purports to provide pain relief through photo biomodulation.<sup>2</sup> Photo biomodulation uses light therapy (the laser) to stimulate multiple signalling pathways and cellular processes to promote healing and reduce inflammation.<sup>3,4</sup> With the use of light energy instead of thermal, no heat is produced resulting in pain-free treatment.<sup>4</sup> Likewise, the use of light energy ensures that only the damaged cells are affected and not healthy cells around the region.<sup>4</sup> Consequently, there are few to no side effects associated with the laser therapy because affected cells undergo biostimulation to promote healing and prevent inflammation.

## Who Might Benefit?

Approximately 8 million Canadians live with chronic pain; approximately 80% of adults will be affected with chronic low back pain at least once in their lifetime.<sup>5,6</sup> People with chronic low back pain experience multiple challenges in different aspects of their lives, including their social, physical, mental, and professional lives.<sup>5</sup> Social interactions can be affected because chronic pain can result in a feeling that others do not understand or believe the pain to be true.<sup>5</sup> This can lead to isolation, which often results in less motivation to seek treatment and support for pain.<sup>5</sup> Physically, people with low back pain can struggle to move around or carry out daily activities.<sup>5</sup> With this comes challenges associated with working; potentially having an

effect on job security. Financially, there is a strain on resources because of investment in treatment and/or a reduced ability or inability to work. All these factors affect the sense of self and can lead to a deterioration of mental health.

People with low back pain often invest in their treatment and seek out a variety of different sources to help with pain relief. Treatment options include pharmacotherapy; psychological interventions, such as support groups, rehabilitative services, spinal manipulation, and mobilization; and alternative medical practices, such as acupuncture.<sup>5</sup> The Erchonia FX 635 may be beneficial to people with low back pain because it is a noninvasive intervention that does not have the adverse effects associated with surgery or pharmacotherapy.<sup>1</sup>

## Availability in Canada

Currently the Erchonia FX 635 is licensed in Canada, with the first issue date in 2018, and the lasers are distributed to health care providers and clinics by Magne-tec.<sup>3,7</sup> This cold laser therapy is currently the only laser type cleared by the FDA for the treatment of low back pain of musculoskeletal origin.<sup>8</sup> It is used in various clinics across Canada; those identified are private pain or chiropractic clinics.<sup>9-11</sup>

## What Does It Cost?

Information on the cost of Erchonia FX 635 in Canada was not identified. However, the price of the laser device in the US is approximately US\$40,000.<sup>12</sup> Specific treatment session costs using the Erchonia FX 635 were not identified but the price of a low-level laser therapy session in a clinic in Canada is \$125 and prices per session range between US\$30 to US\$200 in the US.<sup>12,13</sup> Current treatment protocols suggest patients need at least 8 sessions with their health care provider for treatment to be effective, thus total treatment costs could add up to a minimum of US\$300.<sup>12</sup> The device is fully automated requiring 1 medical professional to set up the device to the required protocol and adjust the arms to the lower back region.<sup>3</sup> As a result of automation, the medical professional or staff can attend to other duties in the clinic while the procedure is ongoing.<sup>3</sup>

## Current Practice

Currently, the approach to treat and manage low back pain involves pharmacotherapy, physiotherapy, rehabilitative services, and psychotherapy.<sup>5</sup> In 2022, the CDC released evidence-based guidance: *Clinical Practice Guideline for Prescribing Opioids for Adult Outpatients With Pain*.<sup>14</sup> In these guidelines, they recommend clinicians maximize the use of nonpharmacologic and nonopioid interventions for patients experiencing pain.<sup>14</sup> For back pain, they note exercise and physical therapy are good nonpharmacologic interventions along with low-level laser therapy, mindfulness-based stress reduction, yoga, and acupuncture.<sup>14</sup>

## What Is the Evidence?

We identified 2 studies examining the use of Erchonia FX 635 for people with low back pain, both of which were associated with the manufacturer.

A randomized, double-blind, sham-controlled study of 58 participants was conducted to determine the effectiveness of Erchonia FX 635 to provide relief of episodic chronic low back pain of musculoskeletal origin.<sup>15</sup> The outcomes studied were a clinically relevant change in visual analogue scale (VAS) pain scores (an improvement or worsening of pain) of at least 30% during the treatment phase and up to 2-month follow-up, change in Oswestry Disability Index score (an increase or decline in disability), and satisfaction from a participant satisfaction survey.<sup>15</sup> Participants were randomized to receive sham treatment with 635 nm LED light or the Erchonia FX 635 active laser for 4 weeks, with eight 20-minute sessions.<sup>15</sup> Overall, 72.4% of participants treated with Erchonia FX 635 had a clinically significant improvement in back pain (as measured on the VAS) compared with 27.6% in participants randomized to the sham device; the difference was statistically significant.<sup>15</sup> Participants treated with Erchonia FX 635 had a higher mean decrease in VAS low back pain, indicating a larger improvement in low back pain, compared with sham-treated participants.<sup>15</sup> Moreover, during the course of the trial, participants treated with Erchonia FX 635 experienced a continual progressive reduction in the mean low back pain VAS score, whereas a smaller, non-clinically relevant decline was noted in participants treated with the sham device.<sup>15</sup> Additionally, participants treated with the Erchonia FX 635 system experienced less disability (reported as a significant decrease in the disability index scores) between baseline and the end of the study. Participants treated with the sham device had experienced a reduction in disability index scores from baseline to the end of the study; however, the reduction was not considered significant.<sup>15</sup> More participants treated with the Erchonia FX 635 were satisfied with the change in low back pain compared with those treated with the sham device; this trend remained at 2-month follow-up.<sup>15</sup> There were no safety concerns identified.<sup>15</sup> It was noted that although the Erchonia FX 635 system was effective at reducing low back pain, its effect on function needs to be studied more closely.<sup>15</sup>

Participants from the randomized double-blind sham-controlled study were followed up at 12 months to determine the effectiveness of the Erchonia FX 635, and showed the therapeutic effects of the laser therapy were maintained after a year.<sup>16</sup> There was a statistically significant decrease in VAS low back pain score from the 2-month follow-up reported in the original trial to the score reported at 12 months.<sup>16</sup> Mean disability scores measured with the Oswestry Disability Index at the 12-month follow-up remained significantly lower than those reported at baseline, which was a clinically meaningful change in disability.<sup>16</sup> At 12 months, all participants treated with the Erchonia FX 635 laser were “very satisfied” or “satisfied” with their change in low back pain.<sup>16</sup> Overall, the authors concluded that laser treatment with Erchonia FX 635 was a safe and effective alternative to pharmacotherapy for low back pain.<sup>16</sup>

## Safety

No safety information was identified in the included studies or reported for the use of Erchonia FX 635 for low back pain.

## Issues to Consider

In 2019, the American Academy of Orthopedic Surgeons released an editorial and noted that orthopedic surgeons may have different levels of awareness and experience related to low-level laser therapy as an intervention for chronic pain.<sup>12</sup> Although there has been great interest in nonpharmacologic interventions for treating pain, this lack of awareness of the technology is something to consider, especially in rural and remote areas where exposure and access to the Erchonia FX 635 may be even further limited.

Currently, the Erchonia FX 635 system seems mostly to be offered in chiropractic or pain clinics which are privately insured or paid out-of-pocket. If not publicly funded, lack of insurance coverage may affect how much it is used by people who experience chronic low back pain and continue to exacerbate inequities related to accessing treatment because current options, such as physiotherapy and psychotherapy, are not always publicly funded. Multiple sessions are needed for a clinically meaningful change to occur with respect to pain so it is important to note that if this low-level laser therapy works well, patients should not have to manage the cost burden for their care.

## Related Developments

A research team in the US has recently conducted a randomized double-blind, placebo-controlled study to determine whether the Erchonia FX 635 can be effective in reducing foot pain associated with diabetes.<sup>17</sup> As of the writing of this report, the results have not been published.

## Looking Ahead

Chronic low back pain continues to affect many people in Canada and around the world and low-level laser therapy is an alternative to pharmacologic interventions that has been used by people with chronic pain. Low-level laser therapy with Erchonia FX 635 is safe and may be effective for people experiencing low back pain.<sup>15,16</sup> With this comes the possibility of an alternative to pharmacotherapy which comes with adverse effects and potential for addiction.

The Erchonia FX 635 system seems to be effective at reducing the morbidity associated with low back pain; however, these have been smaller studies (fewer than 60 adult participants) that have ties to the manufacturer, so more and larger clinical studies need to be conducted to validate and further elucidate the clinical effectiveness of the Erchonia FX 635 laser system. Likewise, studies that compare the Erchonia FX 635 system to active interventions that are used for pain relief would be helpful in determining if the laser therapy can work as an adjunct or standalone intervention. Because the Erchonia FX 635 has been studied

for pain associated with benign origins, studies need to be conducted to determine if it is an effective option for all forms of pain from different etiologies. Depending on the price and effectiveness of Erchonia FX 635, it has the potential to reduce the cost burden associated with treatment for low back pain. However, if the cost burden of treatment shifts to the patient, this could lead to additional disparities in accessing the cold laser therapy. If the Erchonia FX 635 system is something that has long-term effectiveness, it could have a positive effect on people who experience chronic low back pain and may reduce the overall cost of low back pain to the health system.



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