Federal Biomedical Agency

Federal Public Health Institution 'Federal Research and Clinical Centre for Sports Medicine and Rehabilitation at the Federal Biomedical Agency'
(FPHI FRCCSMR FBA)

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30th March 2015

ANALYTICAL REPORT
A PILOT STUDY TO EVALUATE THE EFFECTIVENESS AND SAFETY OF B-CURE ® LASER FOR ATHLETES

Moscow, Russia, 2015

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Introduction

The purpose of this research was to evaluate the clinical effectiveness and safety of **B-CURE ® LASER** medical devices in high-performance athletes.

The research objectives were to assess the clinical effectiveness and safety of **B-CURE ® LASER** devices on the symptoms and progress of osteoarthritis of the knee joint, using a visual analogue scale (VAS) and a verbal rating scale.

Osteoarthritis is a common medical condition affecting 10% of the population worldwide. According to various researchers, osteoarthritis makes up between 30% and 55% of all orthopaedic conditions. It is also known that knee joints are most frequently affected (10%) in over 55s, where one in four becomes severely disabled.

Fairly often, gonarthrosis occurs even in young, able-bodied people, including those engaged in sports and physical work. According to our data, 58% of gonarthrosis patients who underwent joint replacement were under 60 years of age. Therefore, effective treatment for gonarthrosis appears to be not only medically and socially, but also economically important.

According to Russian researchers, knee joint traumas account for nearly 50% of all knee injuries and up to 24% of all lower limb injuries. X-ray identifiable signs of knee joint gonarthrosis are found in 30% of males and females aged 65 and older. Up to 80% of gonarthrosis sufferers experience reduced quality of life, and between 10% and 21% of observed cases result in a disability.

Insufficient research into the degenerative joint disease aetiology and pathogenesis, late diagnosis, a wide range of symptoms and progression pathways, and complications make it extremely difficult to select appropriate treatment. In practice, gonarthrosis sufferers are likely to be offered an off-the-shelf treatment scheme, which includes non-steroidal anti-inflammatory drugs and chondroprotective agents.

When treating gonarthrosis patients, the following should be taken into account:

- risk factors affecting knee joints (obesity, adverse mechanical factors, increased physical activity);
- general risk factors (age, comorbidities, polymedication);
- severity of pain and functional joint impairment;
- signs of inflammation (such as exudation into the joint cavity);
- distribution and extent of structural damage.

Physiotherapeutic treatment of gonarthrosis is applied in order to reduce pain (analgesic effect) and inflammation (anti-inflammatory effect) and to slow down cartilage degradation (structure modifying effect).

Thus, an up-to-date approach to treating degenerative knee joint dystrophic diseases depends primarily on the stage of the disease, where conservative treatments (NSAIDs, chondroprotective drugs) and physiotherapy are the most effective at the initial (1st and 2nd) stages of gonarthrosis.

One of the most common symptoms of knee joint osteoarthritis is myofascial

pain syndrome (MPS), which is caused by damaged striated muscles and associated fibrous structures. It is known that myofascial pain related to a particular muscle has its own distribution pattern specific to this muscle. The pain radiating from the trigger points (TP) is of an unsegmented nature. Trigger points are often activated by injuries.

To detect an active myofascial trigger point, one needs to do the following:

1) identify the pain distribution pattern;
2) see whether there is any rigidity or weakness in the associated or affected muscle and whether the muscle is restricted in its movement;
3) see if there is a tight fibrous knot and whether putting pressure on the tight muscle tissue causes acute local pain;
4) check whether pinching causes a local vascular reaction;
5) see whether dedicated treatment of affected muscles eliminates the symptoms.

Myofascial hypertension develops in several stages. The starting point is residual muscle deformation which occurs when minimal-intensity isometric work is performed over long periods of time. Muscle restructuring distorts the proprioceptive sensation from the hypertonic area. This is followed by distortion of the sensory input coming from both the segmental apparatus of the spinal cord (circular corrective movement organisation) and the suprasegmental structures of the brain (programmable movement organisation). Once movement organisation is distorted, normal movement patterns are replaced with pathological patterns resulting in the fibromyalgia syndrome.

Specifications, Methodology, and Findings

Researchers from the Russian Biomedical Research and Clinical Centre (FPHI FRCCSMR FBA) studied the effectiveness of **B-CURE ® LASER**.

Given below are the key features of the device:

Laser type	GaAlAs	solid laser diode
maximum power		250 mW
wavelength		808 nm
pulse frequency		15 kHz
laser pulse duration		17 μs
energy per minute		3.75 J
laser element dimensions (LxH)		45x10 mm
device dimensions		200x70x40 mm
weight		175 g

The **B-CURE ® LASER** is a low-voltage laser therapy device (for low-level laser therapy, or LLLT) featuring a balanced laser frequency of 808 nm and a maximum pulse power of 250 mW on a contact surface of 4.5 cm^2. The device offers a rechargeable, hand-held design, which is lightweight and easy to operate. Given its power and precision levels, the laser beam from the device is able to effectively penetrate even deep tissues.

Low-level laser therapy (LLLT) relies on applying a low-power laser pulse ranging between 1 and 1,000 mW with a wavelength of 632–904 nm in order to stimulate positive natural biological reactions.

Low-level laser is a concentrated emission of electromagnetic radiation with a wavelength in a very narrow range of the electromagnetic spectrum. This emission is coherent, monochromatic, and polarised, which allows it to penetrate the skin surface without heating or damaging it. A low-level laser beam is cold and non-invasive, which makes it safe to use.

While applying the aforesaid medical device, researchers attempted to evaluate its clinical effectiveness and safety for high-performance athletes suffering from post-traumatic knee joint damage.

Special attention was paid to assessing the effects of **B-CURE ® LASER** devices on the symptoms and progress of knee joint osteoarthritis during its acute phase and when accompanied by the myofascial syndrome.

Experimental Subjects

The research was carried out on members of Russian national teams in various sports. The following sports were represented:

Football – 10 athletes
Rugby – 6 athletes
Greco-Roman wrestling – 2 athletes
Basketball – 2 athletes

Inclusion criteria:

1. Signed the informed consent form.

2. Aged 18 and over.
3. Suffers from osteoarthritis of the knee joint.
4. Has knee joint injury.
5. Experiences a post-surgery condition.
6. Is happy to undergo therapy and receive all the required treatment during the study.

Exclusion criteria:

1. Did not sign the informed consent form.
2. Aged under 18.
3. Is hypersensitive to laser radiation.
4. Suffers from an oncological condition.

Method of Use

The device was used continuously.

Usage and optimal exposure mode:
the device was put into continuous operation with 8 minutes of exposure. The treatment continued for 14 days, excluding weekends (Saturdays and Sundays).

Depending on the severity of clinical symptoms, a repeat course of treatment may be recommended by a doctor.

Stage-by-Stage Findings

The study was conducted in three stages:

1. Initial assessment of the musculoskeletal system using:

- conventional methods of clinical muscle and joint examination applied in orthopaedics/traumatology and physiotherapy;
- questionnaires for assessing pain severity on a visual analogue scale (VAS) and a verbal rating scale.

At its initial stage, the study revealed the following:

- 80% of the monitored athletes made efforts to put less pressure on the injured limb when standing and walking, and complained about pain and awkwardness in the affected knee joint;
- 90% of the subjects experienced functional reduction in the strength of the gluteal muscle group on the same side as the affected knee joint.

The initial assessment of the musculoskeletal system revealed that all patients experienced pronounced pain and irregular movement trajectory of the lower limb when tested in that area.

2. The second stage of the study was carried out after treating the athletes with **B-CURE ® LASER** for 7 days. The following was revealed as a result:

- a 30% pain reduction in all patients
- improved coordination in the affected lower limb

Three athletes who also did physiotherapy as part of their recovery programme, reported that they felt “light” and experienced less pain when doing their physiotherapy exercises.

3. Once their treatment was over (on the 14th day of using the **B-CURE ® LASER**), all athletes revealed a significant increase in flexibility and movement coordination in the affected knee joint. This suggests that the treatment helped various structures of the knee joint to better adapt to exercise.

Table 1. Summary of the Experimental Subjects

Parameter	**Avg. age (years)**	**Gender M/F (number of people)**	**Initial assessment**	**Assessment after using B-CURE ® LASER for 7 days**	**Assessment after using B-CURE ® LASER for 14 days**
			Average pain score on the VAS scale		
Football	24	M – 7	90.03821	46.0294	5.013
		F – 3	85.20352	46.5925	5.005
Rugby	35	M – 4	79.10480	43.0132	5.990
		F – 3	75.92032	44.6938	5.012
Basketball	32	M – 1	77.03843	43.6930	5.034
		F – 1	84.01929	44.5849	5.902
Greco-Roman Wrestling	23	M – 2	87.29420	43.9028	5.011

The athletes reported that during the last week of treatment they experienced almost no pain when performing the moves and exercises that used to cause pain or discomfort earlier.

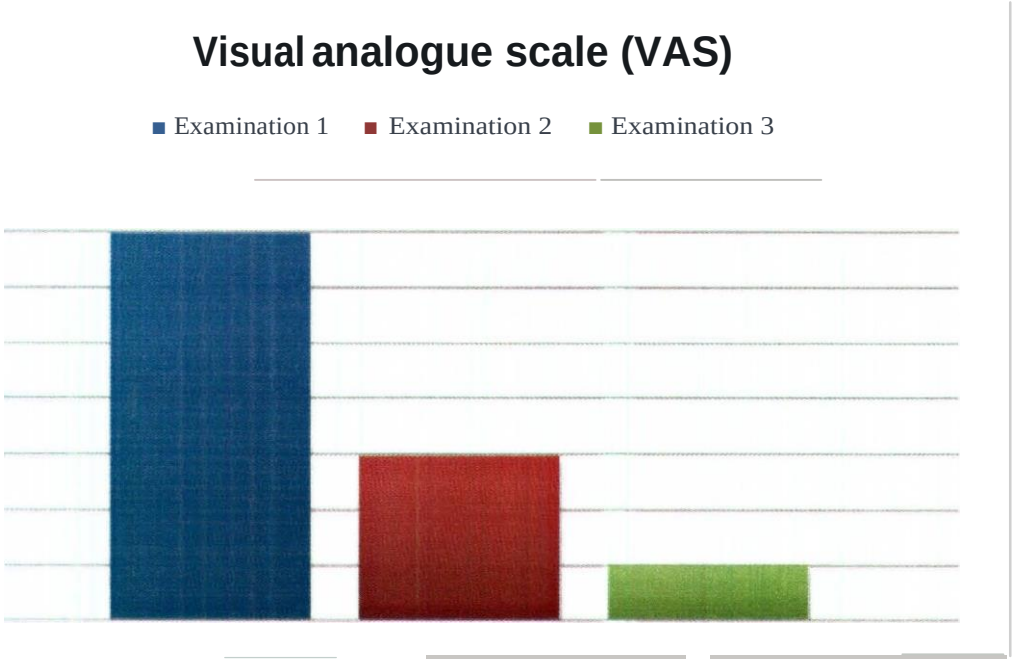

Figure 1. Stage-by-stage pain score distribution on the VAS

Based on the study, the researchers made the following **CONCLUSIONS**:

1. When tested on high-performance athletes, **B-CURE ® LASER** treatment helped improve their wellbeing by eliminating pain and discomfort in the affected joints.
2. The final examination demonstrated improvement in the support function of the affected limb, leading to better proprioceptive control and improved coordination.
3. A course of treatment with **B-CURE ® LASER** helps reduce recovery times in athletes suffering from knee joint osteoarthritis.
4. No side effects were identified when using **B-CURE ® LASER** treatment.

Conclusions

This paper contains an expert study into the effectiveness of **B-CURE ® LASER** treatment in high-performance athletes suffering from osteoarthritis of the knee joint. The study included the following stages:

1. An initial clinical assessment of the participating athletes (including pain assessment scales).
2. A 14-day treatment with **B-CURE ® LASER** (excluding weekends, i.e., Saturdays and Sundays).
3. Once the treatment with **B-CURE ® LASER** was completed, researchers evaluated the orthopaedic status and functional state of the affected knee joints (by using pain assessment scales among other methods).
4. Experts were able to prove the effectiveness of **B-CURE ® LASER** treatment for athletes suffering from osteoarthritis. A final examination of the monitored athletes was also carried out.

The research achieved its purpose and all its tasks were successfully completed. Based on the findings, the team was able to conclude that the **B-CURE ® LASER** is a highly effective medical device for treating high-performance athletes with osteoarthritis of the knee joint.

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