

## **Federal Biomedical Agency**

### **Federal Public Health Institution, Federal Research and Clinical Centre of Sports Medicine and Rehabilitation of the Federal Biomedical Agency**

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### **ANALYTICAL REPORT ON A PILOT STUDY TO EVALUATE THE EFFECTIVENESS AND SAFETY OF THE B-CURE LASER MEDICAL PRODUCT FOR ATHLETES**

Research aim: to evaluate clinical effectiveness and safety of the **B-CURE LASER** medical devices in high-performing athletes.

Research objectives: to assess the impact of clinical effectiveness and safety of the **B-CURE LASER** medical device 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 disease with 10% of the population worldwide suffering from it. According to various authors, the incidence of this pathology among other orthopaedic diseases ranges between 30% and 55%. At the same time, it is known that knee joints are most frequently affected (10%) in over 55s, where one in four becomes severely disabled.

Gonarthrosis often occurs in young, able-bodied people, including those engaged in sports and active employment. According to our data, 58% of patients with gonarthrosis who underwent joint replacement were under 60 years old. Therefore, the problem of effective treatment of gonarthrosis is not only medically and socially but also economically significant.

The members of Russian national teams in various sports were involved in the study. The following sports were represented in the study:

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

#### **Inclusion criteria:**

Patient's signed informed consent.  
Over the age of 18.  
Osteoarthritis of the knee joint.  
Knee joint injury.  
Condition after surgery.  
Intention to receive therapy and all required treatments during the study.

#### **Description of use**

The device was used continuously.

Mode of use and optimal exposure mode: the device was put into continuous operation with eight minutes of exposure. The course of treatment was 14 days, excluding weekends (Saturday and Sunday).

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

### Staged research findings

The study was conducted in three stages:

Initial assessment of the musculoskeletal system: generally accepted methods of clinical muscle and joint examination used in orthopaedics / traumatology and physical therapy;

Questionnaire assessment scales for pain severity on a visual analogue scale (VAS), and pain severity on a verbal rating scale: At this stage of the study, the following has been identified:

80% of the athletes studied protected the injured limb when standing and walking, complained of pain and unsteadiness in the affected knee joint; 90% of the subjects noted functional reduction in the strength of the gluteal muscle group on the homolateral side of the affected knee joint; As a result of the primary assessment of the musculoskeletal system, all patients identified pronounced pain and reduction in the movement trajectory of the lower limb when assessed in that area;

The second stage of the study was carried out after the B-CURE LASER medical device was used for seven days: pain reduction in all patients by 30% improvement in the coordination of the affected lower limb.

Three athletes, receiving a concurrent course of physical therapy as a part of their rehabilitation programme, noticed a sense of "lightness" and a reduction in pain during physical therapy exercises.

By the end of the course (on the 14th day of the use of the B-CURE LASER medical device), all athletes showed a significant increase in fluidity and coordination of movement in the affected knee joint. This result suggests an improvement in the adaptation of various structures of the knee joint to physical stress in the subjects.

Table 1 Allocation of patients taking part in the study

Parameter	Average age (years)	Gender M / F (total number)	Initial assessment	Assessment after the 7 day use of B-CURE LASER	Assessment after 14 day use of B-CURE LASER
			Median 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 remarked that during the last week of treatment they experienced almost no pain in those movements and physical activities which caused pain or discomfort earlier.

## Visual analogue scale

Examination 1 • Examination 2 Examination 3

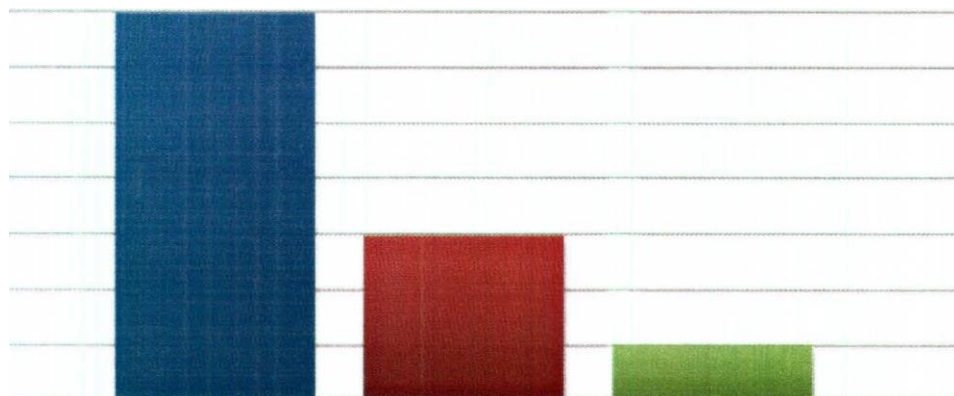


Fig. 1. Score distribution on the VAS scale according to the stage of the assessment

The following **CONCLUSIONS** were made as a result of the study:

The use of the B-CURE LASER medical device in high-performance athletes leads to improved health indications in patients in the form of disappearance of the pain syndrome and discomfort in the affected joint.

The final study demonstrates improvement of the support function of the affected limb, which leads to increased proprioceptive control and improved coordination.

A course of physiotherapy which includes the use of the B-CURE LASER medical device provides a reduction in the rehabilitation period for athletes with the symptoms of the knee joint osteoarthritis.

No side effects when using the B-CURE LASER device were identified.

## Conclusion

Expert effectiveness evaluation of the **B-CURE LASER** physiotherapeutic device for high-performance athletes suffering osteoarthritis of the knee joint was carried out in this study.

The study included:

- Primary clinical evaluation (including the use of pain assessment scale) for high-performance athletes with osteoarthritis of the knee joint.
- A 14-day physical therapy treatment using the B-CURE LASER medical device excluding weekends (Saturday and Sunday).
- An evaluation, using pain assessment scales, of the orthopaedic status and functional status of the affected knee joint after the course of treatment with B-CURE LASER was completed.
- The efficiency of the B-CURE LASER medical device for athletes with osteoarthritis of the knee joint was confirmed and the final examination of this cohort of athletes was carried out.

The research objective was achieved. All specified tasks were completed. The conclusions corresponding to the results of the study were drawn, confirming high effectiveness of the **B-CURE LASER** medical device for high-performing athletes with osteoarthritis of the knee joint.

Study Director

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