

B-CURE[®] LASER

PHOTOMEDICINE and LASER SURGERY

Endorses the efficacy of B-Cure Laser for the treatment of pain and wounds

A recently published Systematic Literature Review (Nov. 2018) in Photomedicine and Laser Surgery Journal, widely supports the outstanding efficacy of B-Cure Laser, vs. all other Photobiomodulation home use medical devices for the treatment of pain and wounds.



**B-Cure Laser cited
in 4 out of 14 studies
according to the
systematic search**

**Table 1. Studies Included According to Systematic Search (Above Dashed Line)
As Well As Abstracts (Below Dashed Line), Ordered by Publication Date**

Study	Year	Design (Grade ^a)	Sample size	Application	Device
Merigo et al. ¹¹	2017	Case series (C)	3	Treating postprocedural oral anesthesia/paresthesia	B-cure diode laser (Good Energies, Haifa, Israel)
Saltmarche et al. ¹²	2017	Case series (C)	5	Improving cognitive dysfunction in Alzheimer patients	Vielight Neuro Alpha—intranasal applicator (Vielight, Inc., Toronto, Canada)
Fornaini et al. ¹⁰	2015	RCT (B)	24	Reducing pain related to temporomandibular disorder	B-cure diode laser (Good Energies)
				Reducing retinal thickness in diabetic retinal edema	WARP10 (Quantum Devices, Inc., Barneveld, WI)
				Improving cognitive dysfunction in TBI patients	MedX Home (MedX Health, Inc., Ontario, Canada)
				Prophylaxis of postscar revision side effects	LumiPhase-R Compact device (Opusmed, Montreal, Canada)
				Prophylaxis of postablative procedure side effects	LumiPhase-R Compact device (Opusmed)
				Improving diabetic sensory neuropathy	Anodyne Therapy Professional System 480 (Anodyne Therapy, Tampa, FL)
				Healing recalcitrant diabetic foot ulcers	3 Anodyne Therapy Professional System 480 (Anodyne Therapy)
				Reducing Herpes labialis lesions healing time	Virulite CS (Virulite LLC, Costa Mesa, CA)
Stelian et al. ¹⁶	1992	RCT (A)	50	Reducing knee pain	Experimental device (Amcor Ltd., Israel)
Hazeh et al. ²⁴	2017	RCT	19	Healing recalcitrant diabetic foot ulcers	B-cure diode laser (Good Energies)
Goo et al. ²⁶	2016	Pilot prospective	10	Reducing symptoms related to menorrhagia	Healite Mini (Lutronic Corp., Goyang, South Korea)
Del Vecchio et al. ²⁵	2016	RCT	90	Reducing pain related to temporomandibular disorder	B-cure diode laser (Good Energies)

^aGrade of recommendation according to the Oxford Centre for Evidence-based Medicine—Levels of Evidence.
^bThis study was published as a full text in 2016.²⁷ | RCT, randomized control trial; TBI, traumatic brain injury.



International guidelines recommend the use of low level laser therapy for treatment of Oral Mucositis

The Multinational Association of Supportive Care in Cancer (MASCC) and the International Society of Oral Oncology (ISOO) have published guidelines that show evidence-based recommendations for low-level laser therapy for treating and preventing Oral Mucositis caused by radiotherapy or chemotherapy.

B-CURE[®]
LASER

HOW DOES B-CURE LASER WORK?

Low-level laser therapy (LLLT) (also known as cold laser) is a laser beam that acts on the surface of the skin and at the same time penetrates deep into the tissue with no heating effect and without damaging the skin. Low-level laser therapy stimulates cell activity, strengthens cell signals and increases the efficiency of the body's natural immune system. It boosts the production of anti-inflammation enzymes, releases endorphins (pain reducing hormones), and increases the formation of collagen and elastin which promotes the healing of wounds and the rehabilitation of the injured area following surgical procedures.

B-CURE LASER BENEFITS

Efficient and speedy treatment:

- Helps reduce pain and swelling
- Shortens recovery time
- Effective for treatment of both acute and chronic wounds and inflammation

Clinically proven

- Over 2000 studies conducted over time prove laser technology to be effective in treating wounds, inflammation, pain, muscle and bone problems
- The use of B-Cure Laser therapy for the treatment of pain, wounds and orthopaedic conditions has been proven in numerous double-blind clinical trials

Natural and safe to use for all ages

- Natural, non-invasive treatment
- Extensive research done in recent decades proves that B-Cure Laser therapy is totally safe to use, does not produce adverse effects, does not cause any damage and poses no risk of overuse

For home use

- Easy and safe to use on a daily basis, in the clinic or at home
- The most advanced technology is packed into a powerful, lightweight portable device. This provides depth of penetration and effectiveness of treatment available until now only through the use of heavy, stationary equipment

Ease of Use

- Use of the device is simple and easy and does not require any specific knowledge or skills nor protective goggles
- Place the device gently on the treated area, set treatment time as recommended in the treatment protocol and the device is ready to start (use a plastic wrap for hygienic purposes)

Global Recognition

- A recently published Systematic Literature Review (Nov. 2018) in Photomedicine and Laser Surgery Journal, widely supports the outstanding efficacy of B-Cure Laser, vs. all other Photobiomodulation home use medical devices for the treatment of pain and wounds. The B-Cure laser appears in 4 of 14 studies (Merigo 2017, Fornaini 2016, Hazez 2017, Del Vecchio 2016), all with successful effective outcomes in pain reduction and wound healing applications.
- The Multinational Association of Supportive Care in Cancer (MASCC), the International Society of Oral Oncology (ISOO) and the National Institute for Health and Care Excellence in the UK (NICE) have published guidelines that show evidence-based recommendations on low-level laser therapy for treating and preventing Oral Mucositis caused by radiotherapy or chemotherapy.

CLINICAL APPLICATIONS

Pain, bone or tissue injuries and orthopedic conditions:

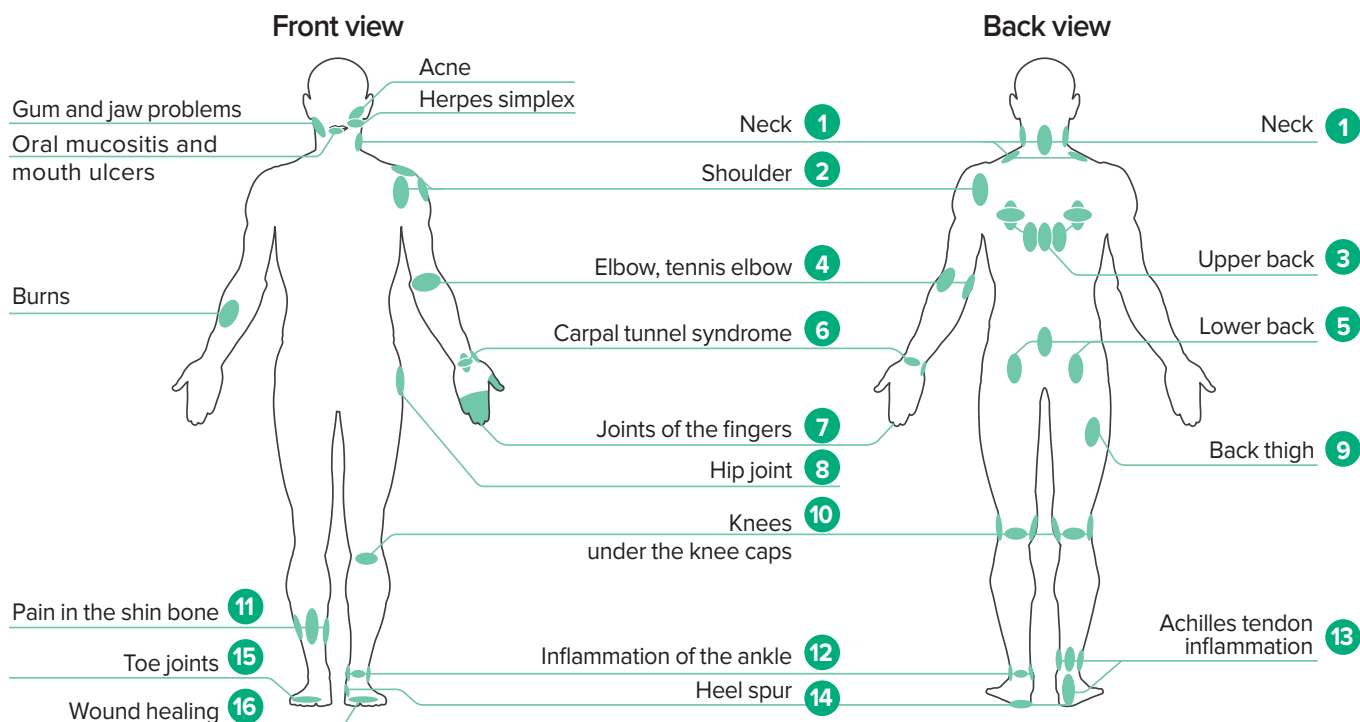
- Back pain: lower back, upper back, neck, and muscle pain
- Joints: knees, hips, shoulders, fingers, Osteoarthritis
- Rheumatoid arthritis, and / or chronic tendon inflammation
- Heel spurs and sprains
- Tennis elbow
- Achilles tendon inflammation
- Carpal tunnel syndrome (CTS)
- Myofascial pain syndromes
- Jaw joints pain - TMJ

Wounds and dermatology

- Diabetic ulcers
- Pressure wounds
- Vascular wounds
- Oral Mucositis and mouth ulcers
- Acne
- Fresh scars and burns
- Promotes improved and more esthetic healing of surgical incisions
- Herpes simplex



TREATMENT AREAS FOR VARIOUS MEDICAL INDICATIONS AND DIRECTION OF THE BEAM



THERAPEUTIC EFFICACY OF HOME-USE PHOTOBIO-MODULATION DEVICES: A SYSTEMATIC LITERATURE REVIEW

Gavish L., Faculty of Medicine, The Hebrew University of Jerusalem, Israel; Houreld N., Faculty of Health Sciences, University of Johannesburg, Johannesburg, South Africa.

B-Cure Laser PBM device is an effective and safe treatment of pain and wounds

Objectives:

Perform systematic literature review on photobiomodulation (PBM) devices used at home for non-esthetic applications.

Background:

Home-use PBM devices have been marketed for cosmetic and therapeutic purposes. This is the first systematic literature review for nonesthetic applications.

Methods:

A systematic literature search was conducted for PBM devices self-applied at home at least thrice a week. Two independent reviewers screened the articles and extracted the data. Treatment dosage appropriateness was compared to the World Association for Laser Therapy (WALT) recommendations. The efficacy was evaluated according to the relevant primary end-point for the specific indication.

Results:

Eleven studies were suitable. Devices were applied for a range of indications, including pain, cognitive dysfunction, wound healing, diabetic macular edema, and postprocedural side effects, and were mostly based on near-infrared, pulsed light-emitting diodes with dosages within WALT recommendations. Regarding efficacy, studies reported mostly positive results.

Conclusion:

Home-use PBM devices appear to mediate effective, safe treatments in a variety of conditions that require frequent applications. Conclusive evaluation of their efficacy requires additional, randomized controlled studies.

Table 1. Studies Included According to Systematic Search (Above Dashed Line) As Well As Abstracts (Below Dashed Line), Ordered by Publication Date

Study	Year	Design (Grade ^a)	Sample size	Application	Device
Merigo et al. ¹¹	2017	Case series (C)	3	Treating postprocedural oral anesthesia/paresthesia	B-cure diode laser (Good Energies, Haifa, Israel)
Saltmarche et al. ¹²	2017	Case series (C)	5	Improving cognitive dysfunction in Alzheimer patients	Vielight Neuro Alpha—intranasal applicator (Vielight, Inc., Toronto, Canada)
Fornaini et al. ¹⁰	2015	RCT (B)	24	Reducing pain related to temporomandibular disorder	B-cure diode laser (Good Energies)
Tang et al. ¹⁷	2014	Case series (C)	4	Reducing retinal thickness in diabetic retinal edema	WARP10 (Quantum Devices, Inc., Barneveld, WI)
Naeser et al. ¹⁹	2011	Case reports (C)	2	Improving cognitive dysfunction in TBI patients	MedX Home (MedX Health, Inc., Ontario, Canada)
Barolet and Boucher ²²	2010	Pilot RCT (C)	3	Prophylaxis of postscar revision side effects	LumiPhase-R Compact device (Opusmed, Montreal, Canada)
Barolet et al. ^{23,b}	2009	Pilot RCT (C)	14	Prophylaxis of postablative procedure side effects	LumiPhase-R Compact device (Opusmed)
Lavery et al. ¹⁸	2008	RCT (B)	69	Improving diabetic sensory neuropathy	Anodyne Therapy Professional System 480 (Anodyne Therapy, Tampa, FL)
Nather et al. ²¹	2007	Case series (C)	3	Healing recalcitrant diabetic foot ulcers	3 Anodyne Therapy Professional System 480 (Anodyne Therapy)
Hargate ²⁰	2006	RCT (B)	32	Reducing Herpes labialis lesions healing time	Virulite CS (Virulite LLC, Costa Mesa, CA)
Stelian et al. ¹⁶	1992	RCT (A)	50	Reducing knee pain	Experimental device (Amcor Ltd., Israel)
Hazeh et al. ²⁴	2017	RCT	19	Healing recalcitrant diabetic foot ulcers	B-cure diode laser (Good Energies)
Goo et al. ²⁵	2016	Pilot prospective	10	Reducing symptoms related to menorrhagia	Healite Mini (Lutronic Corp., Goyang, South Korea)
Del Vecchio et al. ²⁵	2016	RCT	90	Reducing pain related to temporomandibular disorder	B-cure diode laser (Good Energies)

^aGrade of recommendation according to the Oxford Centre for Evidence-based Medicine—Levels of Evidence.

^bThis study was published as a full text in 2016.²⁷ | RCT, randomized control trial; TBI, traumatic brain injury.

B-CURE LASER - A NEW HOME PROTOCOL OF LLLT IN PATIENTS AFFECTED BY JOINTS RELATED PAIN *(Paper Submitted)*

Del Vecchio A., Fioravanti M., Boccassini A., Di Paolo C., Romeo U.

Department of Oral and Maxillo Facial Sciences | Sapienza University of Rome, Italy

Results of a randomized, double blind, placebo controlled clinical trial conducted on 90 patients

B-Cure Laser's efficacy is almost equivalent to the conventional drugs therapy

Introduction and Background:

Starting from the widely accepted and clinically demonstrated efficacy of the Low Level Laser Therapy in the management of the pain related to TMJD, this study investigated about the possibility to obtain the same positive results with a new home LLLT protocol, based on the self-administration of the therapy. It was designed at a high level in the pyramid of evidence: Randomized, Double blind, Placebo controlled Clinical Trial.

Materials and Methods:

Patients cohort: 90 consecutive patients affected by TMJD referring at the Department of Oral and Maxillo Facial Sciences of Sapienza, University of Rome randomly subdivided into 3 groups.

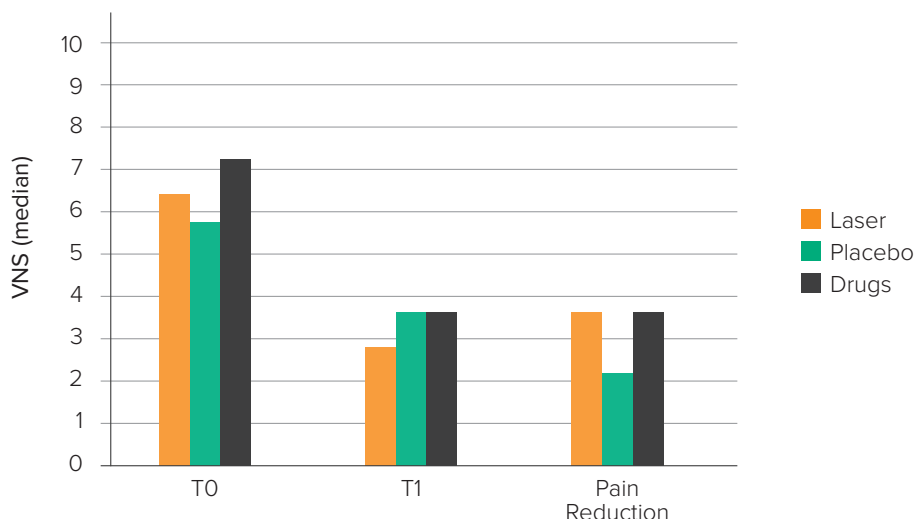
Study Group (SG) patients (n=30) effective LLLT: B-Cure Laser Dental Pro (808nm, Low Level Diode Laser, Good Energies, Israel), applied over the painful area twice a day, for 1 week. Each application was performed at 5 J/min, 250mW at peak and 15KHz for 8 min. for a total of 40 J each. A LLLT skilled operator performed the first application, while patients themselves performed the remnants at home.

Placebo Group (PG) patients (n=30) sham device: Same protocol than SG, with a sham device, devoid of the main laser source and with the sole indicator light, furnished by the same manufacturer.

Drug Group (DG) patients (n=30): Conventional drug therapy adopted at the department for the TMJD related pain: 2 non consecutive cycles of 5 days of Nimesulide (100mg/day), interspersed with one 5 days cycle of Cyclobenzaprine Hydrochloride (10mg/day).

A pain evaluation was requested by examiner immediately before the laser treatment (T0) and at the end of the treatment (T1= 7 days) For the pain evaluation was adopted the Verbal Numeric Scale 0-10 (VNS). After the treatment all the patients received the conventional therapy for the resolution of the TMJD.

Results:



Conclusion:

The LLLT home protocol can be considered an effective and safe method to manage the pain related to TMJDs. B-Cure Laser's efficacy is almost equivalent to the conventional drugs therapy. The LLLT has no adverse local or systematic effects. The real extent of the placebo effects need further investigations with larger cohorts of patients and lower numbers of laser applications.

B-CURE LASER: LOW LEVEL LASER THERAPY PREVENTS COMPLICATIONS POST LAMINECTOMY *(Submission in process)*

Holanda V., Pereira B., Ferreira K., Greiffo F., Oliveira J., Franca C., Silva D., Ontaneda M., Pinto N., Chavantes C. | Beneficência of Sao Paulo Hospital, Nove de Julho University, Sao Paulo, Brazil

B-Cure Laser, in comparison with the placebo group, stimulates better wound healing, significantly reduces pain level, inflammation and drainage output

Background:

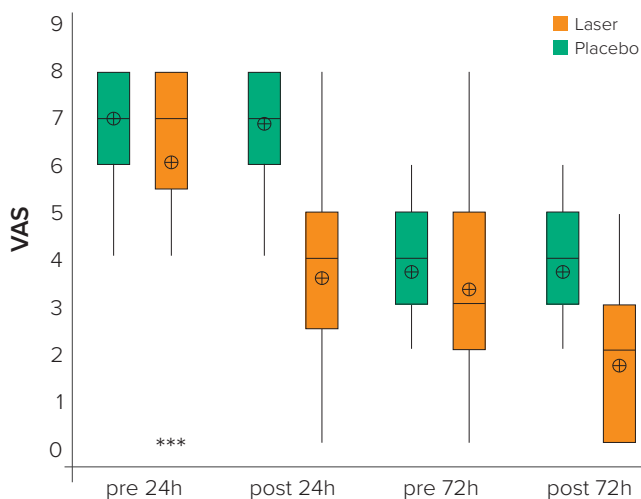
Every year, over one million individuals worldwide are submitted to laminectomies, with a rate failure higher than 40%. Post laminectomy epidural adhesion is implicated as a main cause of “failed back surgery syndrome” and associated with high risk of complications during the revision surgery. The objectives of this project are to delineate and evaluate the LLLT effects in spinal surgery.

Study:

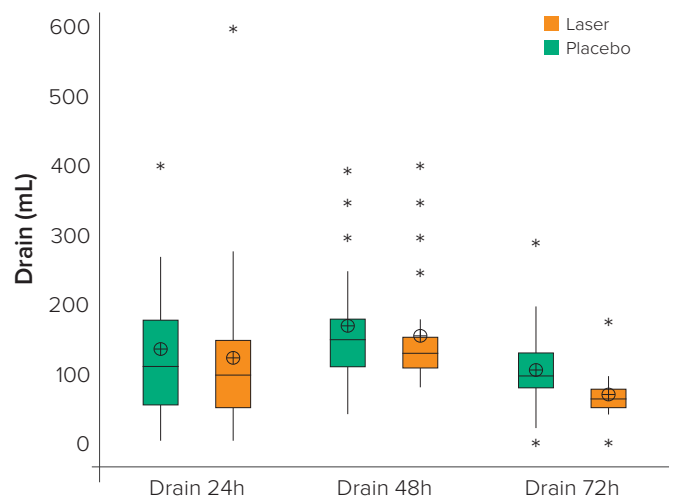
A prospective randomized, controlled trial with a total of 46 patients, undergoing laminectomy, were divided into 2 groups. In 23 randomized patients, LLLT (B-Cure Laser, GOOD Energies, Israel), diode laser-semiconductor Gallium Arsenide and Aluminum (GaAlAs) was applied during surgery (808 nm, total exposure time of 240 seconds, energy density of 2.48 J/cm², average power of 62.5mW, spot area of 3,876cm²), for 60 seconds on the laminectomy site, 60 seconds in the subcutaneous tissue and 120 seconds over the wound. In addition, LLLT was applied on the wound site in 24 hours and 72 hours after surgery*. In the second group, 23 patients were induced to think they were getting the same treatment, although LLLT was not operating.

Results:

The results showed a decrease of temperature, pain relief and accelerated healing in laser group, LLLT facilitates wound healing, due to a more rapid resolution of acute inflammation, as suggested by the CRP biggest drop from second to fifth postoperative day, and the proliferation phase of healing to begin earlier demonstrated statistically significant values by more rapid fall in the laser group of CK, suggesting that these markers may guide LLLT treatments.



*Graph 8. Visual Analogue Scale (VAS). (24h p = 0.0001) (72h p = 0.0001).



*Graph 9. Evaluation of drain exudate. (24h p = 0.421) (48h p = 0.332) (72h p = 0.004).

Conclusion:

In conclusion, we demonstrate that only three applications of LLLT stimulate better wound healing, reduce inflammation in the wound bed, decrease drainage output and assist in postoperative analgesia in spinal surgery.

*<https://bibliotecatede.uninove.br/bitstream/tede/1148/2/Vanessa%20Milanesi%20Holanda.pdf>

HEALING OF CHRONIC DIABETIC FOOT ULCERS USING B-CURE LASER PRO - LOW LEVEL LASER THERAPY (LLLT)

(Submission in process)

Haze A., Elishoov O., Liebergall M.

The Division of Orthopedics, Hadassah Medical Center, Jerusalem, Israel

12 weeks of daily B-Cure Laser Pro treatments significantly decreased wound size in patients with diabetic foot ulcers compared to the sham laser group

Background:

Diabetes mellitus (DM) is a significant health concern affecting hundreds of millions of individuals worldwide. A diabetic person has a 25% lifetime risk of developing a diabetic foot ulcer (DFU), which may lead to limb amputation and risk patient's life. The cellular and molecular effects of LLLT on wound healing were studied, though solid clinical effects on DFU healing is still lacking. The current study is a double blinded randomized trial evaluating the effects of a home use LLLT device (B-Cure Laser Pro, Israel) on DFU healing.

Methods:

19 patients, suffering for at least 6 weeks from a DFU, sized 3-37.5cm² were recruited. Patients were randomly assigned to daily treatments of LLLT (808nm, 8 minutes, 9 J/cm²) (experimental group, n=10) or sham (control group, n=9) in addition to standard of care dressing. The treatment period lasted 12 weeks or until wound closure.

Results:

Initial wound sizes were 11.2±11.1cm² in the control group and 12.4±9.2 in the experimental group. At the endpoint wound sizes were 6.5±7.3 and 1.5±2.4. Using 2-sided exact Wilcoxon Sign Ranks test no significant difference was found between the initial wound sizes of the groups (p=0.92) and also between the initial and final wound sizes in the control group (p=0.301). Significant difference was found between the initial and final wound sizes in the experimental group (p=0.002). Direct comparison of percentage of wound closure between the experimental and control groups showed a significant healing effect of laser over sham (p=0.033). 7 of 10 active patients vs 1 of 9 placebo patients had >90% wound closure (p=0.019 by Fisher Exact Probability Test).

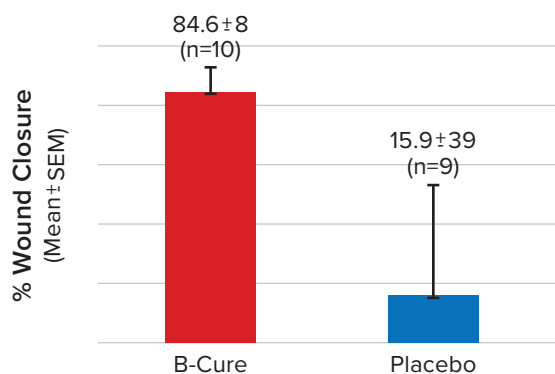


Figure 1: %Wound Closure – B-Cure vs Placebo

Table 2: improvement > 90%

Improvement	Active	Placebo
Less than 90%	3 (30%)	8 (89%)
More than 90%	7 (70%)	1 (11%)
Total	10	9

Placebo vs Active baseline: P=0.019 by Fisher Exact Probability Test

Conclusions:

In spite of the relatively small groups the results show that B-Cure Laser Pro may be beneficial as an adjunctive treatment to standard care for DFU healing. Further studies are warranted to strengthen our conclusions.

B-CURE LASER DENTAL PRO TECHNOLOGY FOR PREVENTION AND TREATMENT OF PERI-IMPLANT MUCOSITIS

Gileva O., Libik T., Chuprakov M., Yakov A.

Municipal Dental Clinic No. 2 and the Department of Therapeutic and Preclinic Dentistry, Ministry of Health Care of the Russian Federation (Perm), Russia

The use of B-Cure Laser in prevention and treatment regimens before and after Dental Implantation significantly reduces the frequency and intensity of the pain symptoms and oral mucosal postoperative hematomas in comparison with the sham laser group

Abstract:

Oral mucositis (OM) is the severe inflammation, lesioning and ulceration of the epithelia, accompanied by bleeding and intensive pain. OM is a common complication of dental implantation. Low-level laser therapy (LLLT) has been found to enhance the repair and healing of epithelia. The aim of this study was to evaluate the effectiveness of preventive and treatment use of LLLT (B-Cure Laser Dental Pro) in the patients who have undergone dental implantation. Simple blind randomized prospective one-center comparative placebo.

Background:

In recent years, dental implants confidently retain the status of a leading trend in modern dentistry, making a serious alternative to the traditional techniques of fixed and removable prosthetics of dental defects, providing high aesthetic and functional results and improving the quality of life of the dental patient. However, the possibility of early and late postoperative complications of dental implantation (DI) did not entirely eliminate and may reduce the success of implant treatment, and therefore it requires adequate prevention, early detection and correction. For the prevention and treatment of inflammatory and sensory-paresthetic complications of DI low-level laser therapy (LLLT) having multifactorial local and systemic effects on the patient is reasonably used.

Materials and Methods:

Single-blind randomized prospective single-center comparative placebo-controlled clinical trial to study the efficacy of LLLT by defocused beam of B-Cure Laser Dental Pro device in the complex events of the surgical phase of DI in prosthetic treatment of patients with partial edentulism was held in the period from June to October 2016.

30 patients (13 men and 17 women aged 28 to 57 years) with included defects of tooth alignment of various location and extent, with indications and intentions for prosthetic treatment with the use of DI. Monitoring groups for the comparative placebo-controlled trial were formed by the method of restricted randomization: the laser group —LG, the patients in the complex of dental implantation received “active” LLLT, generating the corresponding laser radiation by B-Cure Laser Dental Pro device, and the placebo group - PG, the patients received “inactive” placebo B-Cure Laser Dental Pro device with an identical exterior design and handling characteristics, simulating the generation of LLLT and with specific, understandable only by the dentist encoding. The patients of LG used a portable laser therapeutic dental devices B-Cure Laser Dental Pro (Good Energies®, Israel)—Ga-Al-As diode laser generated infrared laser radiation (wavelength—808 nm, power—250 mW, pulse frequency—14 kHz) with unfocused beam 4.5 cm u 1.0 cm with a power density of 14.4 J/min at the peak (3.2J/cm² per minute). The device has the necessary international certificates (CE 0120—Medical Device), approved for the use in the field of healthcare. At the baseline (T0), on the 2–3 (T2-3), 5–7 (T5-7), 10–14 (T10-14) days and 3 months (T90) after the operation of DI the structure, the frequency and severity of complications in early and late postoperative period were analyzed in the patients.

The complex of LLLT using B-Cure Laser Dental Pro technology was carried out in “preventive” (at preoperative stage) and in “treatment mode” (at postoperative period) modes. LLLT in “preventive mode” were conducted

by a trained dentist in the dental office using contact, stable technique, transcutaneously in the projection of dentoalveolar segments corresponding to the DI installation location; a course of 2-3 procedures daily, with a duration of 8min. LLLT in the “treatment mode” was carried out by a trained patient at home on the next day after the operation of DI by the following method: contact, stable area of irradiation (4.5 cm²) of the skin in the projection of the dentoalveolar segment(s) corresponding to the area of DI. The sessions of laser therapy (2) were carried out after the operation on a daily basis, lasting for 8 min (total exposure time—16 min.), the course—7–10 days. Optional LLLT was carried out by the patient at the stage of gingival formation using contact, stable technique, transcutaneously in the projection of DI: daily, duration of the procedure—8 min, treatment course—3–5.

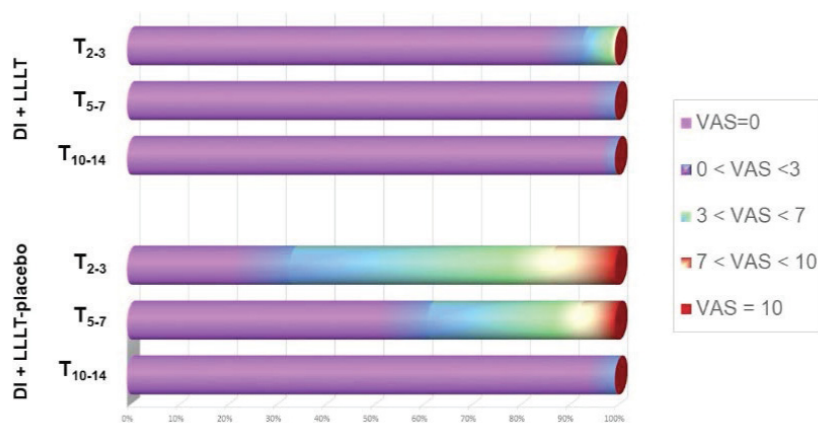


FIGURE 1. The magnitude of pain (VAS scores) and the restructuring of the pain symptom in patients of compared groups in postoperative period of dental implantation stages (T2-3–T10-14)

Results:

Two thirds (66.7%) of the patients in PG noted local inflammation (swelling, redness) in the area of implantation, mostly slightly or moderately expressed. The symptoms of local, mainly slight, inflammation, in periimplantation area were revealed (Fig.2) only in 20.0% of the patients at T2-3, i.e. 3.3 times less than in PG. The frequency of occurrence of oral mucosal postoperative hematomas on T2-3 in the patients of PG was significantly ($p < 0.05$) higher than in the patients of LG, (33.3% versus 13.3%, respectively), including the vast, exciting area of 1-2 jaw segments and adjacent areas of oral mucosa and lips (Fig. 3), often continuing for 5 days after surgery. On T2-3 in the absolute majority of PG patients mouth opening was restricted in comparison with the initial values (29.32 ± 4.40 mm versus 45.50 ± 6.22 mm; $p < 0.05$).

Conclusion:

The results of the study are consistent with the known data that dental implantation in some cases can create problem situations for the doctor and the patient, manifested a steady and severe pain symptom, orofacial swelling, etc.

The use of original LLLT techniques in prevention and treatment regimens before and after DI significantly (in 3.5 times) reduces the frequency and intensity of the pain symptom in the first days after the installation of endosseous implants, promotes earlier and more complete relief without additional analgesics within the first 5 days of the postoperative period in comparison with placebo-laser therapy.

The inclusion of LLLT in DI complex by 3.3– 3.7 times reduces the frequency, duration and intensity of local edema-inflammation in preimplantation area and edema of soft tissues, prevents the development of clinical functional and aesthetic disorders, associated with limitation of mouth opening throughout the surgical stage of DI. The data confirms the information that in some patients early postoperative DI may be accompanied by pronounced physical and psychological discomfort, pain symptom, functional and aesthetic disorders, manifested by a decrease in dental dimensions of quality of life. Effective relief of swelling pain and sensory-paresthetic symptoms as well as associated aesthetic, functional and psychological disorders on the background of LLLT allows minimizing subjective feelings of reduced quality of life in the early postoperative period.

B-CURE LASER: THE "AT-HOME LLLT" IN JOINTS RELATED PAIN CONTROL: A PILOT STUDY

Fornaini C., Pelosi A., Queirolo V., Vescovi P. and Merigo E.

Department of Biomedical, Biotechnological and Translational Sciences (S.Bi.Bi.T.), University of Parma, Italy

B-Cure Laser group experienced a 50% decrease in pain level within two weeks compared to 8% in the sham laser group

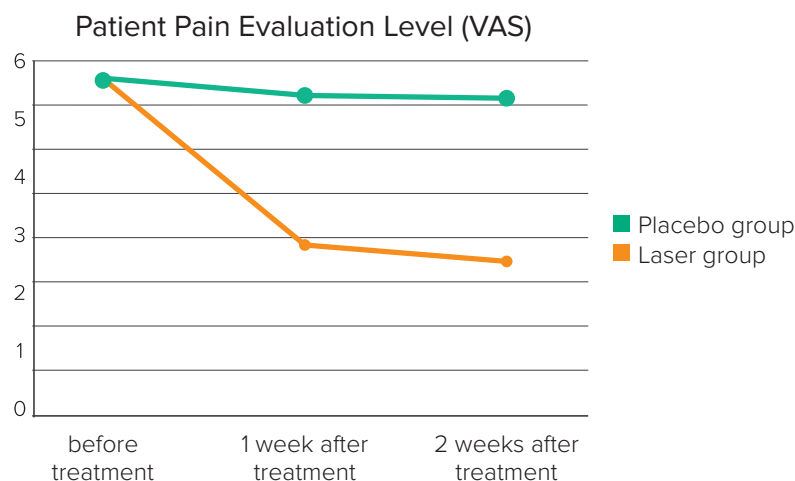
Objectives:

The Temporomandibular Disorders (TMD) are a set of dysfunctional patterns concerning the temporomandibular joints (TMJ) and the masticatory muscles; its main symptom is pain, probably caused by inflammatory changes in the synovial membrane, alterations in the bone marrow of the mandibular condyle and impingement and compression. The aim of this preliminary study was to investigate the effectiveness in the TMD pain reduction of a new laser device recently proposed by the market that, due to its reduced dimensions and to be a class I laser according the ANSI classification, may be used at home by the patient himself.

Materials and methods:

Twenty-four patients with TMD were randomly selected: the inclusion criteria for the sample was the diagnosis of mono- or bi-lateral TMD, with acute pain restricted to the joint area, associated with the absence of any muscle tenderness during palpation. The patients were randomly assigned to two groups: Group 1 (12 patients): patients receiving real LLLT (experimental group). Group 2 (12 patients): patients receiving inactive laser (placebo group). The treatment was performed once a day for two weeks with an 808 nm diode laser (B-Cure Laser, Good Energies, Israel), by the patient himself with irradiation of the cutaneous zone corresponding to the TMJ for 15 minutes each side. Each patient was instructed to express its pain in a visual analogue scale (VAS) making a perpendicular line between the two extremes representing the felt pain level. Statistical analysis was realized with GraphPad Instat Software, where $P < 0.05$ was considered significant and $P < 0.01$ very significant.

Results:



The patient's pain evaluation was expressed in the two study groups before the treatment, 1 week and two weeks after the treatment. The differences between the two groups result extremely significant with $p < 0.0001$ for the comparison of VAS value after 1 and 2 weeks

Conclusion:

This study, even if it may be considered such a pilot study, investigated a new way to control the pain in the temporomandibular diseases by an at home self administered laser device. Results are encouraging but they will have to be confirmed by greater studies.

A CROSS-SECTION POST MARKETING SURVEY TO EVALUATE CUSTOMER EXPERIENCE AND SATISFACTION AFTER USING THE B-CURE LASER DEVICE

Prof. Avi Degani, Geocartography Knowledge Group,
analysis by Gavish L., Faculty of Medicine, The Hebrew University of Jerusalem, Israel

Background:

Low level laser therapy (LLLT) is widely used for the treatment of a variety of inflammatory related conditions. The B-Cure Laser is a home-use LLLT device that is sold in Europe and Asia for management of acute and chronic pain, as well as wound healing. To date, five small successful prospective double-blind randomized sham-controlled clinical trials were conducted with the device. Adverse events related to the device were not reported in any of these studies. In view of these encouraging results from prospective controlled clinical trials, the company intended to evaluate the real-life experience and customer satisfaction with the device.

Methods:

To that end, a phone survey was conducted by Geocartography Knowledge Group that specializes in customer surveys. The company was given a database of 10,000 coded numbers representing patients that purchased the device at least 3 months prior to the survey, with the intention to survey a sample of 300. After collecting demographic information, the customers were asked about the indication for which they used the device, the frequency of use and its timing, perception of the pain before and after using the device, satisfaction with the device, duration of pain relief, and side effects/adverse events.

Results and Discussion:

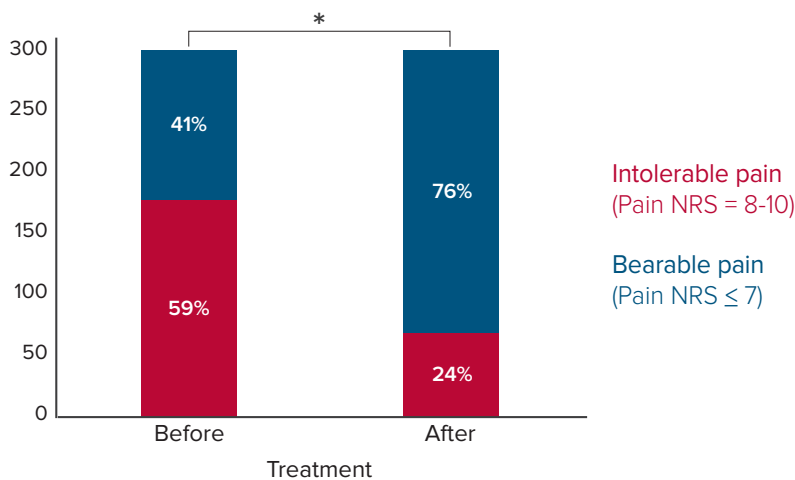


Figure 1: Proportion of customers with intolerable pain before vs after the treatment

60% of the patients who suffered from intolerable pain (8-10 NRS) have experienced a significant decrease to a bearable pain ($p < 0.0001$ by chi square) (Figure 1).

“The secret of change is to focus all of your energy not on fighting the old, but on building the new”

- Socrates



max 250 mW at peak 808 nm	International breakthrough Israeli Patent + IP	Patented electro optic mechanism emits a fully coherent most efficient pulsed beam
	- 4.5 cm ² of coherent - therapy -	

© Apr 2019 | ORTHOPEDIC and PAIN BOOKLET_IS

B-CURE®
LASER