B-CURE® LASER PRO

For an effective treatment of **DIABETIC FOOT ULCERS** and **WOUNDS**

PHOTOMEDICINE
and LASER SURGERYEndorses the efficacy of B-Cure Laser
for the treatment of pain and wounds

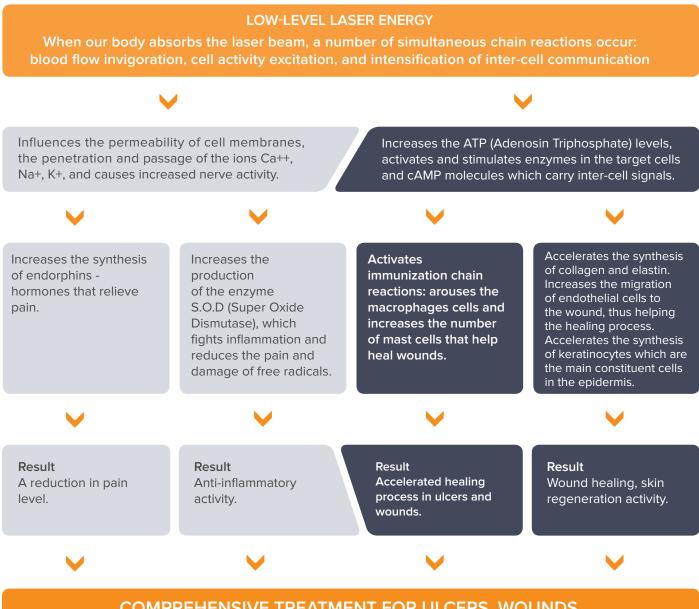
A recently published Systematic Literature Review (Nov. 2018) in Photomedicine and Laser Surgery Journal, widely supports the outstanding efficacy of B-Cure Laser, vs. all other Photobiomodulation home use medical devices for the treatment of pain and wounds.





HOW DOES B-CURE LASER PRO 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 tissues 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.



COMPREHENSIVE TREATMENT FOR ULCERS, WOUNDS, PAIN, INFLAMMATIONS AND ORTHOPEDIC CONDITIONS

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 inflammations

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 wounds, orthopaedic conditions and pain 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 effectivenes 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 googles
- Place the device as nearest to the wound without touching it, set treatment time as recommended in the treatment protocol in the brochure 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, Hazeh 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.

RECOMMENDED PROTOCOL

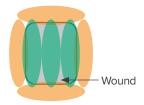
B-Cure Laser Pro is an adjunctive treatment to the standard of care. Dressing must be removed before starting treatment.

Wound Margins: Every dressing replacement (daily treatment recommended, max. once a day): begins with 2 min. per application for the first 2 weeks and if there is no improvement, increase to 3 min. per application. When treating the wound margin, the beam should also cover 2 mm. of the wound bed outer edge (see illustration)

Wound Bed: Every dressing replacement (daily treatment recommended, max. once a day): begins with 0.5 min. per application for the first 2 weeks and if there is no improvement, increase to 1 min. per application. The number of applications to be performed is according to wound size (see illustration)

Inguinal and Popliteal Lymph Nodes: Apply daily on both lymph nodes of the wounded leg (max. twice a day): 1 min. per each application

Wound Margins and Wound Bed





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 ± 11.1 cm² 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).

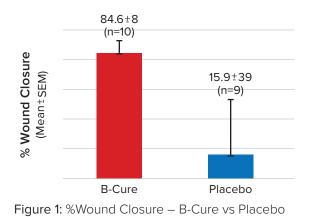


Table 2: improvement > 90%	Table	2:	improvement >	90%
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Improvement	Active	Placebo
Less than 90%	3 (30%)	8 (89%)
More than 90%	7 (70%)	1 (11%)
Total	10	9

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.

PHOTOS TAKEN OF PATIENTS FROM THE CLINICAL TRIALS









THERAPEUTIC EFFICACY OF HOME-USE PHOTOBIOMODULATION 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 demonstrates effective safe treatment of pain and wounds

Objectives:

Perform systematic literature review on photobiomodulation (PBM) devices used at home for nonesthetic 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.

Study	Year	Design (Gradeª)	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. 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)

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

^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.

SELF USE LOW-LEVEL LASER THERAPY TO ACCELERATE HEALING OF HARD TO HEAL WOUNDS WITH VARIOUS ETIOLOGIES

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Aim:

Evaluation of consumer home-use Low-level laser therapy or Photobiomodulation (PBM) as an as an adjuvant to standard treatment to accelerate healing of acute and/or chronic wounds PBM device*.

Method:

Patient were recruited from clinic: 16 cases (11:5 male:female, 43-84 years old) included 3 abdominal wounds, 5 diabetic foot ulcers (DFU), 2 dehisced limb incisions, 3 Venous leg ulcers, and 3 complicated wounds, were treated from May to November 2018. The PBM treatment (808nm, 250mW peak power, 15KHz, 5J/min, ray size 4.5×1.0cm2) was applied over the wound bed, wound margins, and over nearby lymph nodes by the patients themselves.

Results / discussion:

The abdominal wounds achieved complete epithelialization after 5-6 treatments at the clinic over a period of 9-21 days. Three of the DFUs closed within 2 weeks after 4-6 treatments and the other 2 achieved 50% size decrease in 1 week. 3 complicated wounds were improved or completely resolved with significant pain alleviation between one to 3 days. Finally, out of 3 recurrent extremely painful not responding to combination pain medication venous ulcer pain resolved in all within a week treatment however accelerated healing was less significant than in other ulcer types.

Conclusion:

Hard-to-heal wounds are a burden for patients, caregivers, and costly for the healthcare system. Based on our previous experience and the cases presented here, self-applied PBM, led to accelerate healing and rapid pain alleviation over standard care alone. Moreover, the treatment encouraged patient's involvement in own care.



*B-Cure Laser PBM device

EVALUATION OF 5 HOSPITALS IN ISRAEL SHOW THAT B-CURE LASER PRO ACCELERATES DIABETIC FOOT ULCER HEALING

Analysis by Gavish L., Faculty of Medicine, The Hebrew University of Jerusalem, Israel

Introduction:

The global prevalence of diabetes is steadily increasing and with it the prevalence of diabetic foot ulcers [1]. The current standard of care for complete closure is 25% in 12 weeks [2] with the initial ulcer size playing a significant role [3]. The B-Cure laser is a home-use photobiomodulation therapy (low-level laser) device that is sold in Europe and Asia for management of acute and chronic pain, as well as wound healing. In a double-blind randomized sham-controlled clinical trial Haze et al., showed that daily B-Cure Laser Pro treatments for 12 weeks as an adjunctive treatment to standard of care, significantly decreased wound size in patients with diabetic foot ulcers (DFU) compared to sham irradiated controls [4]. In view of these encouraging results, the company set to evaluate the real-life experience with the device.

Methods:

Data was collected from patients with diabetic foot ulcers from outpatient clinics of 5 different medical centers in Israel. The sample consisted of patients of both genders, aged over 18 years old that were initially given standard of care treatment and used as an adjunctive treatment B-Cure Laser Pro device during March to November 2018. Patients self-applied the laser (808nm, 250mW peak power, 15KHz, 5J/min, ray size 4.5×1.0cm2) at home daily or every other day over the wound bed, wound margin and related lymph nodes (popliteal and inguinal of affected leg - twice a day). The treatment duration was 14min – 64min according to the wound size. Patients who did not return for a follow up check-up were not included in the analysis. Data obtained included demographic information, medical history, and wound size using the ruler method. The wound was photographed adjacent to a ruler before beginning the treatment and at visits to the clinic. Wound closure was confirmed by the treating physician.

Results:

Thirteen (n=13) patients (9 males, 4 females, 53-92 years old) each with a single DFU of variable initial wound size (1.5-15.8 cm2) were included in this analysis. One patient that did not return for a follow up was excluded from the analysis. **Ten of the twelve wounds completely closed**, seven of the twelve wounds, completely closed in 3-12 weeks after beginning laser treatment, 3 wounds completely closed in 14-24 weeks, and 2 wounds are still being treated (Table 1). Using Kaplan Meier survival analysis, the median time for complete closure was 11 weeks, with a mean time of 12.4 weeks [95%CI: 8.0, 16.8]. None of the wounds increased in size during the treatment time and the patients or the treating physician did not report any adverse events related to the laser treatment.

Conclusions:

Patient	Hospital	Wound type	Starting Date	Base line (cm ²)	Last measurment (cm ²)	% Closure	Time (Weeks)
1	А	DFU	07/05/2018	2	0	100	10
2	А	DFU	14/05/2018	1.6	0	100	5
3	А	DFU	22/06/2018	12	0	100	14
4	А	DFU	22/06/2018	3	0	100	3
5	В	DFU	13/08/2018	12.3	0	100	11
6	В	DFU	20/08/2018	6	2.3	62	18
7	С	DFU	30/04/2018	15.8	0	100	24
8	С	DFU	28/03/2018	8	0	100	21
9	С	DFU	21/05/2018	1.5	0	100	8
10	D	DFU	08/11/2018	11.5	4.3	62	4
11	D	DFU	23/10/2018	10.9	0	100	4
12	E	DFU	17/06/2018	5	0	100	12

B-Cure laser Pro treatment as an adjuvant to standard care seems to be a valuable tool for acceleration of wound healing in hard-to treat diabetic foot ulcers.

Table 1: Wound Data Summary

Patient 1, 92, male, Hospital A, diabetes type II, chronic ulcer present for 6 months, initial size 2cm²

After 6 weeks, the patient reduces the amount of the pain killers by 75%. The wound closed in 10 weeks.



Patient 2, 78, Male, Hospital A, diabetes type II, chronic ulcer present for 2 months, initial size 12cm²

The wound achieved 97% wound closure at 12 weeks (12 cm2 to 0.4 cm2) and a complete wound closure at 14 weeks.



References:

- 1. Jeffcoate, W.J., et al., Current Challenges and Opportunities in the Prevention and Management of Diabetic Foot Ulcers. Diabetes Care, 2018. 41(4): p. 645-652.
- 2. Margolis, D.J., J. Kantor, and J.A. Berlin, Healing of diabetic neuropathic foot ulcers receiving standard treatment. A meta-analysis. Diabetes Care, 1999. 22(5): p. 692-5.
- 3. Ince, P., F.L. Game, and W.J. Jeffcoate, Rate of healing of neuropathic ulcers of the foot in diabetes and its relationship to ulcer duration and ulcer area. Diabetes Care, 2007. 30(3): p. 660-3.
- 4. Hazeh, A., et al., Abstract: Healing of chronic diabetic foot ulcers using low level laser therapy (B-Cure laser), in The 37th Annual Meeting of the Israel Orthopaedic Association. 2017: Tel-Aviv, Israel.



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B-CURE LASER: EVALUATION OF THE EFFICACY OF A NEW LOW-LEVEL LASER THERAPY HOME PROTOCOL IN THE TREATMENT OF JOINT-RELATED PAIN (TMJD): A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED CLINICAL TRIAL

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

Objectives:

This study analyzed a home, low-level laser therapy (LLLT) protocol to manage temporomandibular joint disorders (TMJDs)-related pain.

Methods:

Ninety TMJD patients (12M, 78F) between 18 and 73 years were randomly subdivided into three groups. Study group (SG) received 1-week home protocol LLLT by B-cure Dental Pro: 808 nm, 5 J/min, 250 mW, 15 KHz for 8', 40 J each, over pain area, twice daily. Placebo group (PG) followed the same protocol using sham devices. Drugs group (DG) received conventional drugs. Pain was evaluated by visual analog scale (VAS) before and after therapy.

Results:

An analysis of variance (One-Way ANOVA) was performed to compare the mean pain decrease in SG, DG, andPGpatientsbetweenT0andT1.Resultsindicatedthat theeffectofthetreatmentwassignificant(F(2,83)=4.882; p = .010). Post-hoc analysis (Bonferroni test) showed that the mean decrease in pain in the **PG group was significantly lower than both SG (p < .05)** and DG (p < .05). No difference was found between the SG and DG groups (p = 1.000) (Table 5). In the SG, a pain reduction between T0 to T1, of a mean of 34 VAS points per patient was registered. Additionally, in the PG, a mean pain decrease of 25.6 points was found. Finally, in the DG, a mean reduction of pain of 35.3 points was noted per patient. **This preliminary evaluation showed that LLLT and drug therapy have almost the same efficacy in the treatment of pain related to TMJDs (Table 4)**.

Table 4. Mean VAS reduction between T0 and T1 in thethree groups.

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	Ν	Mean	Standard deviation
SG	29	35.17	22.139
PG	28	22.14	16.635
DG	29	36.55	18.181
Total	86	31.40	20.010

Table 5. Bonferroni test shows that the values in PG werelower than both SG and DG.

(I) Group	(J) Group	Means difference (I-J)	Standard error	Significance
SG	PG	13.030*	5.075	.036
	DG	-1.379	5.030	1.000
PG	SG	-13.030*	5.075	.036
	DG	-14.409*	5.075	.017
DG	SG	29	5.030	1.000
	PG		5.075	.017

VAS: Visual analog scale; T0: Immediately before treatment; T1: After treatment; N: Number of subjects; SG: Study group; PG: Placebo group; DG: Drugs group.

SG: Study group; PG: Placebo group; DG: Drugs group.

Conclusion:

According to the results obtained, it is possible to answer positively to the main query of the study, since the pain reduction obtained in the SG was significant. Concerning the answers to the two secondary queries, it is possible to affirm that the efficacy of the laser treatment is very promising, **being at the same level of the one registered in the DG.** The study supports the efficacy of home LLLT management of TMJD related pain.

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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:

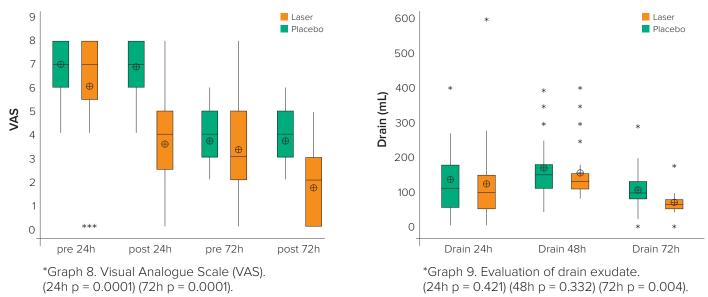
Every year, over one million individuals worldwide are submitted to laminectomies, with a rate failure higher than 40%. Post laminectomy epidural adhesion is implicated as a main cause of "failed back surgery syndrome" and associated with high risk of complications during the revision surgery. The objectives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



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

"The secret of change is to focus all of your energy not on fighting the old, but on building the new" - Socrates



Patented electro optic mechanism emits a fully coherent most efficient pulsed beam

