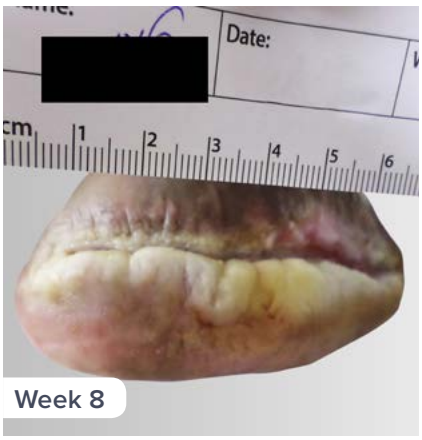
Efficacy of B-Cure® Laser Pro therapy for the treatment of diabetic ulcers and hard-to-heal wounds

• Clinical Trials • Case Studies • Doctors' Reviews

B-CURE® LASER PRO



Index

What is B-Cure Laser Pro?
B-Cure Laser Pro is a device based on an Israeli development and patent which has made a breakthrough in the field of wound healing and treatment of diabetic ulcers. Soft laser treatment encourages healing by stimulating the body's natural cellular activity, strengthening inter cellular communication and stimulating blood circulation.

The Results:
B-Cure Laser Pro shows significant efficacy in treatment of diabetic ulcers and hard-to-heal wounds.

How does B-Cure Laser treat our body?

LOW LEVEL LASER ENERGY
When our body absorbs the laser beam, a number of simultaneous chain reactions occur: blood flow invigoration, cell activity excitation, and intensification of inter-cell communication

Influences the permeability of cell membranes, the penetration and passage of the ions Ca++, Na+, K+, and causes increased nerve activity.

Increases the ATP (Adenosin Triphosphate) level, activates and stimulates enzymes in the target cells and cAMP molecules which carry inter-cell signals.

Increases the synthesis of endorphins - hormones that relieve pain.

Result:
A reduction in pain level.

Increases the production of the enzyme S.O.D (Super Oxide Dismutase), which fights inflammation and reduces the pain and damage of free radicals.

Result:
Anti-inflammation activity.

Activates immunization chain reactions: arouses the macrophages cells and increases the number of mast cells that help heal wounds.

Result:
Accelerated healing process in ulcers and wounds

Accelerates the synthesis of collagen and elastin. Accelerates and induces blood flow to the wound using endothelial cells. Accelerates the synthesis of keratinocytes which comprise the main component of the epidermis.

Result:
wound healing, skin rejuvenating activity.

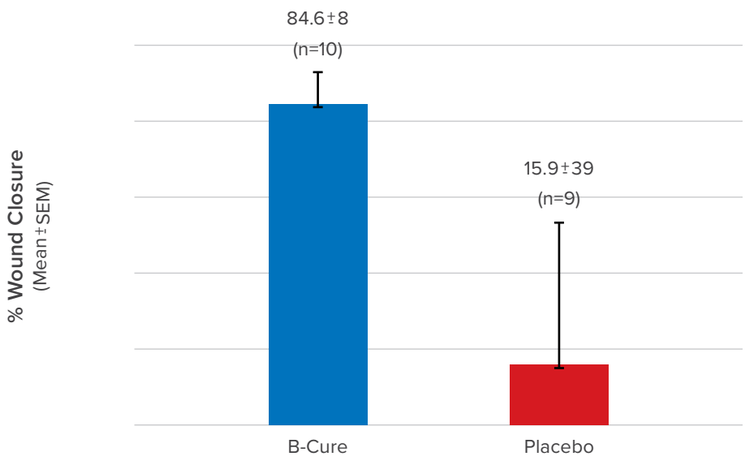
Comprehensive treatment for ulcers, wounds, pain and orthopedic conditions

Clinical trials

B-Cure Laser Pro

Promising clinical trial results for diabetic foot ulcer patients

Facing the epidemic of diabetes, with estimation of 415 million cases (at 2005), we are looking at a problem that lay significant burden on patients, families and health care systems throughout the world. We are excited to show the promising results of a double-blind clinical trial which proved B-Cure Laser Pro's significant efficacy - complete closure of severe and deep diabetic ulcers, up to 24 cm^2, within 12 weeks.



Comparing % closure-Placebo vs Active:P=0.033 by 2 sided exact Mann-Whitney U test. Both groups were treated in addition with gold standard care's same dressings.

Preliminary results of the B-Cure double blind clinical trial show: within up to 12 weeks of treatments - 7 out of 10 patients which received the active B-Cure Laser Pro had >90% wound closure. 4 of them had a complete closure of the wound. In the placebo group, only 1 out of 9 patients had >90% wound closure. p=0.019 by Fisher Exact Probability Test.

B-Cure Laser Pro is also significantly effective to treat pressure wounds, cuts, burns, and post operation wounds.

Technology & Product:

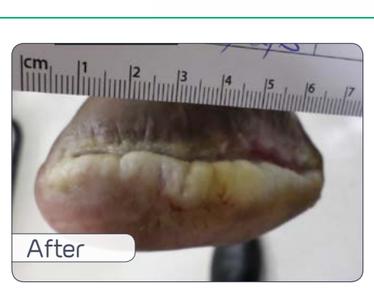
B-Cure Laser Pro is a technological breakthrough, an Israeli development and patent, recommended by leading specialists, for both in-clinic, and home self-treatment.

The patented development is an exclusive electro-optic mechanism which combines a high energy level and full coherence of the laser beam, covering a large area of 4.5 cm^2, in a portable, rechargeable, safe and easy-to-use device. The result is the fast healing and recovery of damaged tissues.

B-Cure Laser Pro may help change the future of treatment protocols for diabetic ulcers and hard to heal wounds as a crucial addition to the standard care. With its fast healing results, low price, accessibility and convenience of use, the B-Cure Laser Pro offers bright future to so many patients.

Great results for post-op treatments, for better looking scars and faster healing and rehabilitation.

Clinical trial results show: complete closure of severe and deep diabetic ulcers, within 8-12 weeks



2.2 The global burden of diabetic foot disease

The global burden of diabetic foot disease

Andrew J M Boulton, Loretta Vileikyte, Gunnel Ragnarson-Tennvall, Jan Apelqvist

Diabetic foot problems are common throughout the world, resulting in major economic consequences for the patients, their families, and society. Foot ulcers are more likely to be of neuropathic origin, and therefore eminently preventable, in developing countries, which will experience the greatest rise in the prevalence of type 2 diabetes in the next 20 years. People at greatest risk of ulceration can easily be identified by careful clinical examination of the feet: education and frequent follow-up is indicated for these patients. When assessing the economic effects of diabetic foot disease, it is important to remember that rates of recurrence of foot ulcers are very high, being greater than 50% after 3 years. Costing should therefore include not only the immediate ulcer episode, but also social services, home care, and subsequent ulcer episodes. A broader view of total resource use should include some estimate of quality of life and the final outcome. An integrated care approach with regular screening and education of patients at risk requires low expenditure and has the potential to reduce the cost of health care.

As the world is facing an epidemic of type 2 diabetes and an increasing incidence of type 1 diabetes[1,2] the International Diabetes Federation has chosen to focus on the global burden of diabetic foot disease in 2005. The lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25%,[3] and it is believed that every 30 seconds a lower limb is lost somewhere in the world as a consequence of diabetes.[4] The International Diabetes Foundation has therefore declared that now is the time to increase awareness of foot problems in diabetes[5] in view of the vast personal, social, medical, and economic costs of what should be one of the most preventable long-term complications of diabetes.[6]

The burden of diabetic foot disease is set to increase in the future since the contributory factors to foot disease, such as peripheral neuropathy and vascular disease, are present in more than 10% of people at the time of diagnosis of type 2 diabetes,[7] and the first year after diagnosis of diabetes is a period of danger for foot ulcers and amputations.[8] Moreover, the greatest rise in the prevalence of type 2 diabetes is likely to be in developing countries in Africa, Asia, and South America,[1] countries in which foot ulcers are more likely to be of neuropathic origin[9] and therefore highly preventable.[10] The challenge facing the global diabetes community is how best to implement screening, educational, and treatment programmes in every region of the world. In this Review we describe the epidemiology and economic consequences of diabetic foot disease across the world and speculate how we might best implement simple screening and preventive educational programmes.

Epidemiology of diabetic foot disease

Global collaborative studies

Given the evidence that the provision of a foot-care service can be associated with a reduction in amputations in diabetic patients,[11] a collaborative group was formed 10 years ago with the aim of comparing the incidence of amputations between communities across the world.[12] In their first report, this group described pronounced differences in amputation rates with the highest in native Americans and the lowest in Madrid, Spain (43·9 *vs* 2·8 per 100 000 per year); diabetes was associated with 25–90% of all amputations.[13]

Other collaborative groups have reported differences in diabetic foot ulcers between developed and developing countries[9] and within different European countries.[14] However, direct comparisons are difficult because of differences in populations studied and time periods over which data were obtained (table).

2·2
..
2·1
0·6
1·9
..
..

2.2 The global burden of diabetic foot disease - Continued

	Year	n	Prevalence		Incidence	
			Ulcers	Amputations	Ulcers	Amputations
Population (community) based studies						
UK[15]	2002	9710	1·7	1·3	2·2	..
Greece[16]	2002	821	4·8	..	..	..
Netherlands[17]	2002	665	..	..	2·1	0·6
Slovakia[18]	1997	1205	2·5	..	0·6	0·6
USA[19]	1999	8965	..	..	1·9	0·3
Clinic-based studies						
Algeria[20]	1998	865	11·9	6·7	..	..
India[21]	1998	11300	3·6	..	..	..

Table: **Epidemiology of foot ulceration and amputations by country**

Search strategy and selection criteria

We based this review on our knowledge of the topic, extensive consultations with members of the International Working Group on the Diabetic Foot, and a comprehensive review of the relevant published work. We cross-checked information with searches on PubMed for articles recently published in the past 10 years using the index terms "diabetes", "neuropathy", "peripheral vascular disease", "foot ulcer", "amputation", "epidemiology", and "health economics".

Lancet 2005; 366: 1719–24

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2.3 Low-level Light Therapy for Treatment of Diabetic Foot Ulcer: A Review of Clinical Experiences

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Abstract

BACKGROUND: Diabetic foot ulcers (DFU) represent a significant complication of diabetes mellitus (DM). DFU affect one in four patients with DM and treatments of DFU are limited and challenging. The management of DFU remains a significant healthcare and socioeconomic burden ($245 billion). There is a wide range of advanced therapies for DFU, but these are costly and have demonstrated only minimal efficacy in limited published studies. An emerging treatment modality to improve DFU and optimize wound healing is the use of low-level light therapy (LLLT). LLLT involves the use of light in the form of low-level or low-power laser or light emitting diodes to alter biochemical pathways, which may result in changes to cell shape, cell migration, and cell signaling.

OBJECTIVE: To review published clinical experiences (case series and case reports) using LLLT for treatment of DFU, and provide evidence-based recommendations and future directions on the potential of LLLT as a therapeutic modality for DFU.

METHODS AND MATERIALS: On January 16, 2016 we searched the published literature using databases: PubMed, EMBASE, CINAHL, and Web of Science with key terms: "diabetic foot" AND ("low level laser therapy" OR "low level light therapy" OR "LLLT" OR "light emitting diode" OR "phototherapy" OR "laser").

RESULTS: After screening of titles, abstracts and/or full-text, 7 original articles were suitable in our review. Our review contains 5 case series and 2 case reports that evaluated LLLT for treatment of DFU, and all reviewed studies have shown positive improvement of DFU using LLLT with no adverse events, albeit with limitations that may be minimized with future RCTs.

CONCLUSIONS: LLLT is an emerging and promising treatment modality to current alternatives that are costly and have shown limited success. Based upon the published evidence, we envision additional research may allow for stronger recommendation with LLLT for treatment of DFU.

J Drugs Dermatol. 2016;15(7):843-848.

2.4 A Pilot Study to Evaluate the Efficacy of Class IV Lasers on Nonhealing Neuroischemic Diabetic Foot Ulcers in Patients With Type 2 Diabetes

A Pilot Study to Evaluate the Efficacy of Class IV Lasers on Nonhealing Neuroischemic Diabetic Foot Ulcers in Patients With Type 2 Diabetes

Giuseppe Maltese,[1] Janaka Karalliedde,[1] Helen Rapley,[2] Tim Amor,[2] Alpa Lakhani,[2] and Luigi Gnudi[1]

Diabetes Care 2015;38:e152–e153 | DOI: 10.2337/dc15-0774

Diabetic foot ulcers (DFUs) represent a disabling complication of diabetes that has a devastating impact on the quality of life and predict lower-limb amputation and premature mortality (1). Despite best practice, 30–40% of DFUs do not heal within 12–20 weeks (2). Novel therapeutic agents have been tested in clinical trials, and it has been estimated that ~30–50% of patients with neuropathic DFUs receiving these new treatments have healed by 12–20 weeks (3). Laser therapy, delivered with devices emitting one or two wavelengths, has been reported as an adjunctive procedure that promotes the healing of chronic diabetic wounds by increasing the blood flow and the release of growth factors and by reducing the inflammation (4).

In this pilot study, we have been the first to investigate the efficacy of an advanced class IV laser (emitting four wavelengths) on Wagner stage 1 and 2 neuroischemic DFUs of five patients with type 2 diabetes who were nonresponsive to conventional treatment for at least 12 weeks. Laser treatment was delivered once a week prior to standard care and dressing. As a control we selected patients with similar DFUs and clinical characteristics treated within our department with standard care. In the laser-treated group, age was 58.2 ± 3.6 years (mean ± SEM; range 47–66) and mean duration of diabetes was 20.4 ± 2.1 years. At the time of enrollment, glycosylated hemoglobin (HbA_{1c}) was 9.0 ± 0.8% (74.6 ± 8.4 mmol/mol). All laser-treated patients had preserved renal function (estimated glomerular filtration rate [eGFR] 72 ± 8.3 mL/min/1.73 m^2) and moderate to severe peripheral artery disease, defined as 20–49% and 50–99% diameter reduction in at least one of the arterial segments from aorto-iliac to popliteal segments on an arterial duplex scan. The mean size of the ulcers was 2.4 ± 1.0 cm^2. The control group of six patients with type 2 diabetes received standard care and had similar ulcer duration and size; comparable glycemic control, age, diabetes duration, and eGFR; and similar degree of peripheral artery disease (Table 1). Standard care for DFUs, including antibiotic treatment, dressing, and off-loading, was similar in both groups. Within the 12-week follow-up, four of five laser-treated patients (80%) had a complete ulcer resolution (most ulcers healed after 4.6 weeks). In the control group, no ulcer healing occurred by week 12.

A limited number of small clinical trials and case studies evaluating the effects of laser devices with lower power and one or two wavelengths on DFUs have previously reported positive outcomes (4). However, because of the heterogeneity in the methodology, findings from these studies have not been consistent. The laser used in this pilot study is the first example of a high-powered device with four wavelengths concomitantly acting on multiple metabolic processes that accelerate the wound healing: stimulation of cytochrome-C oxidase, an increase in angiogenesis, and improvement in blood perfusion (5).

Taking into consideration the limitations of this proof-of-concept study, our findings indicate that laser therapy delivered by a class IV laser can significantly impact the healing process of neuroischemic DFUs refractory to standard treatment. Randomized controlled clinical trials with this new laser device in larger populations are required to confirm our results.

Acknowledgments. The authors thank all patients who participated in this study, K-LaserUSA and VBS Direct Ltd. for providing the laser equipment, and Antonella Chierchia for her technical contribution to the study.

K-LaserUSA had no role in the design, data analysis, or preparation of the manuscript.

Duality of Interest. No potential conflicts of interest relevant to this article were reported.

Author Contributions. G.M. managed the patients, researched the data, and wrote the manuscript. J.K. and L.G. reviewed the manuscript and contributed to the discussion. H.R., T.A., and A.L. delivered foot care and administered laser therapy. G.M. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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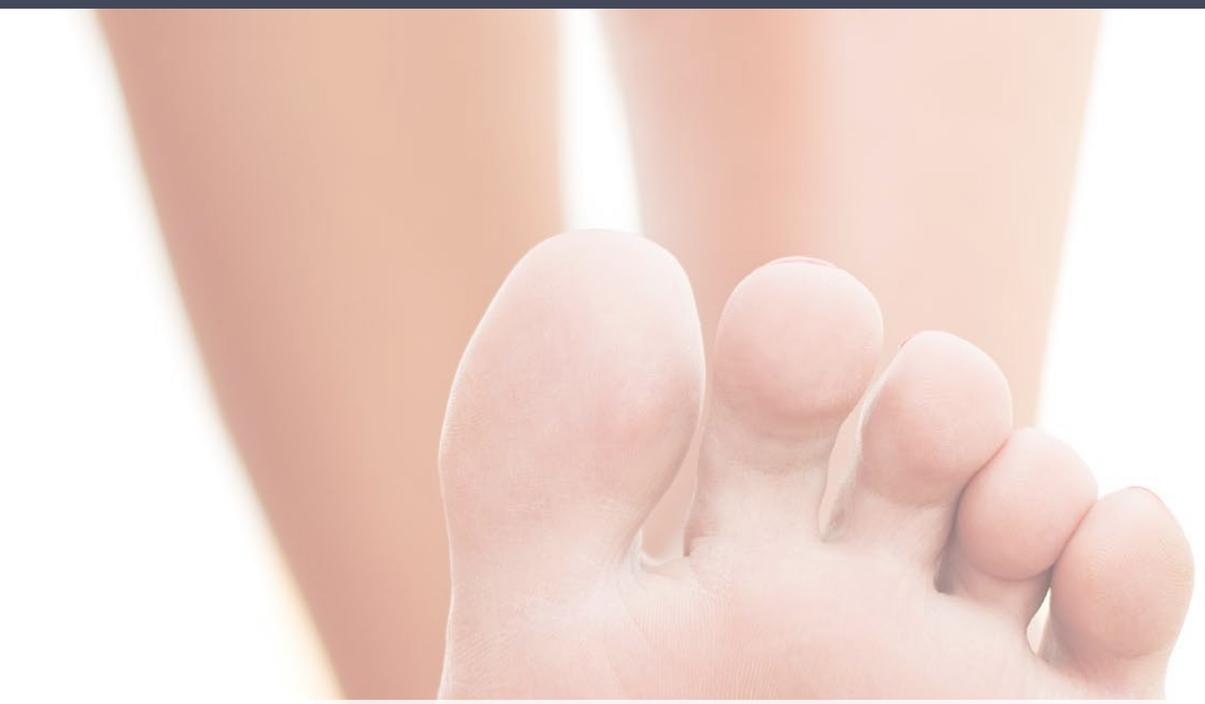
2.4 A Pilot Study to Evaluate the Efficacy of Class IV Lasers on Nonhealing Neuroischemic Diabetic Foot Ulcers in Patients With Type 2 Diabetes - Continued

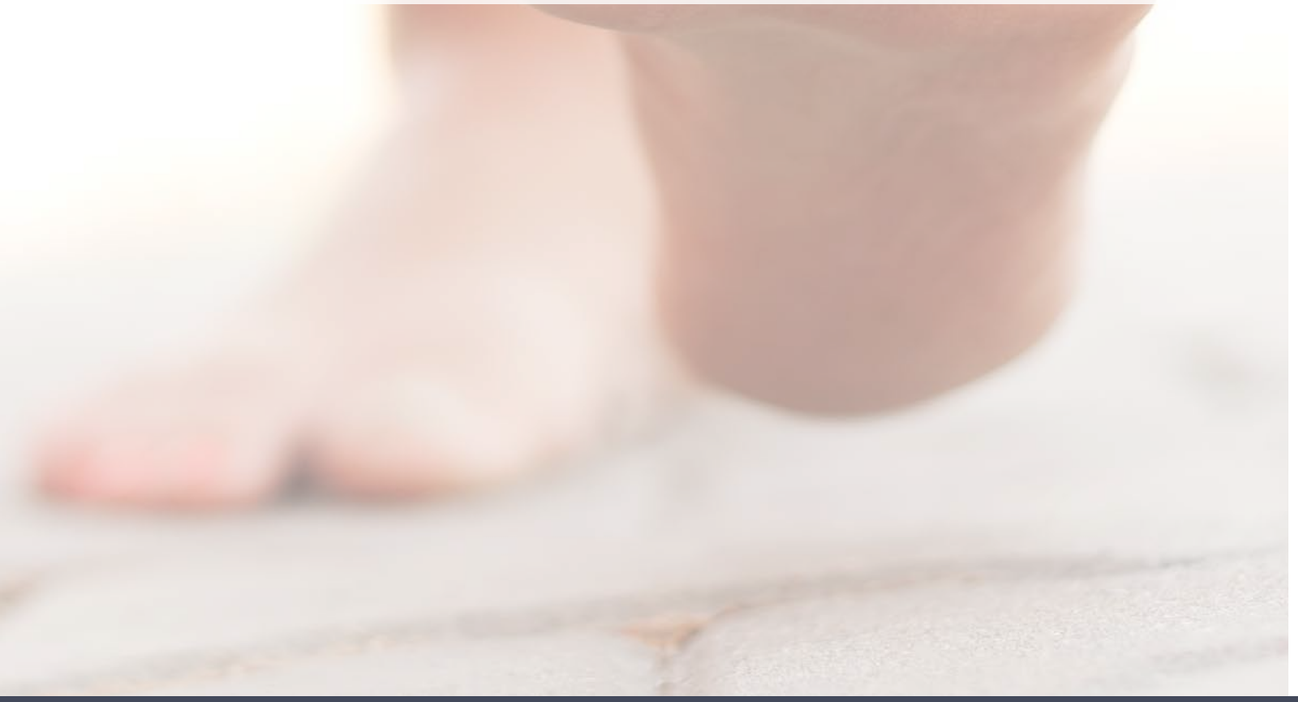
Table 1—Patient characteristics and study outcomes

	Laser + standard treatment	Standard treatment
n	5	6
Sex (male/female)	5/0	5/1
Age (years)	58.2 ± 3.6	63.2 ± 5.1
Duration of diabetes (years)	20.4 ± 2.1	13.8 ± 3.0
HbA_{1c} [% (mmol/mol)]	9.0 ± 0.8 (74.6 ± 8.4)	8.1 ± 0.9 (65.2 ± 10.3)
eGFR (mL/min/1.73 m^2)	72 ± 8.3	65.2 ± 10.3
Duration of ulcers (weeks)	18 ± 2.3	17.3 ± 1.2
Ulcer area (cm^2)	2.4 ± 1.0	2.2 ± 0.5
Patients with complete healing in <12 weeks	4/5	0/6

Data are *n* or mean ± SEM.



Case studies and doctors' reviews



מרכז גריאטרי משולב " בית יפה לגיל הזהב"
MEDICAL GERIATRIC CENTER "YAFFE HOME FOR GOLDEN AGE"
NATHANYA, HERZOG STR. 25 נתניה, הרצוג 25

Case Study using B-Cure® Laser Pro

The Patient:
A 93 year old woman with age-related decreased functionality without known significant medical history, for research, showing no edema in the legs; Skin peeling, a skin tear wound on the calf

Course of treatment:
The wound was treated for 5 minutes; Since local treatment had been unsuccessful, we introduced the B-Cure® Laser treatment device and there was then a significant gradual improvement
Treatment began on 16:01:15 and ended 13.03.15
Total treatment time - 56 days

Result:
Visible progress can be seen in the photos of the wounds - after several days with the beginning of a scab, showing that the healing process was reasonable. It should be noted however, that during the treatment a secondary infection appeared slowing down the pace of the process of healing. Taking into consideration the slow blood flow in a geriatric patient, we witnessed the healing process without added medication, other than a sterile dressing to the wound.

Professional conclusion:
I hereby recommend using the B-Cure® Laser device in combination with conventional treatment for wound healing problems that present in the geriatric population.

Medical Manager
Dr. Ze'ev Fidelman
Specialist in Internal Medicine and Geriatrics, Professor Emeritus

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Case Study using B-Cure® Laser Pro

Anamnestic case history:
101-year-old woman suffering from chronic heart failure, edema in the legs, skin peeling on her calves with secondary infection.

Course of treatment:
5 minute treatments per lesion, one wound was left untreated as a control for study. Photos were taken.

Duration of treatment:
One Month
You can clearly see the fast healing and the emergence of more connective tissue in the early stages.

Result:
Photos indicate the benefit to the wounds and the appearance of scabbing only after a number of days.

Photo before treatment (one of the three wounds)

Photo after a week of treatment

Photo after 30 days treatment

Professional conclusion:
I recommend using the B-Cure® Laser device for the treatment of difficult to heal geriatric sores in conjunction with conventional medication.

Medical Manager
Dr. Ze'ev Fidelman
Specialist in Internal Medicine and Geriatrics, Professor Emeritus

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וגריאטריה,
פרופסור אמריטוס

3. Case studies - Diabetic foot ulcers and hard healing wounds

מרכז גריאטרי משולב " בית יפה לגיל הזהב"
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Case Study using B-Cure® Laser Pro

Anamnestic case history:
A 91 year old woman functioning poorly; a cardiac patient who had been presenting severe leg wounds for more than six months, multiple superficial wounds on both thighs.

The course of treatment:
The resident was treated once a day, for about 2 minutes per wound for three months.

Professional conclusion:
Although the rate of progress of the healing was slow, it should be emphasized that this was due to the vascular problems stated.
From the beginning of the treatment the healing process was quite fast, considering that the above-mentioned sores began last July.
Now all that is left of these chronic wounds is a dry scab.

Photos before treatment

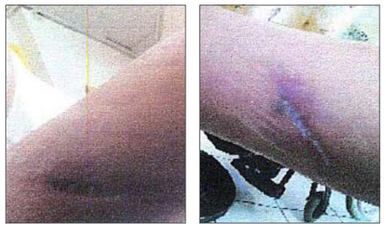

Photo after 2 days treatment

Photo after 3 month treatment

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Case Study using B-Cure® Laser Pro

Anamnestic case history:
A man of 82, an amputee suffering from diabetes, accompanied by severe neuropathy;

Complaint:
Pain in the area of the amputation VAS-7

Process of treatment:
For a month, four minutes of treatment for each of the focal points in combination with conventional treatment.

Results:
After a week improvement - reduction of pain level from VAS 7 to VAS 1.

Professional conclusion:
In light of these findings I can recommend the use of B-Cure® Laser Pro, as a supporting treatment device in conjunction with "conventional" medicine for pain relief.

Medical Manager
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Specialist in Internal Medicine and Geriatrics, Professor Emeritus

ד"ר זאב פידלמן,
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July 15, 2013

TO: The Ministry of Defense, Tel Aviv
Re: Treatment of IDF Disabled Veterans with Soft Laser Therapy

Greetings,

In the light of my past experience with soft laser treatments during the last 23 years, and my acquaintance with the scholarly literature on the subject, I was asked by Mr. Michael Schlosser to prepare background and indications in order to examine the possibility of introducing home-use soft laser devices for IDF disabled veterans.

Background
During the long history of medicine, many sages and healers predicted the healing power of the sun, "But for you who revere my name the sun of righteousness shall rise" (Malachi, 3, 20), and many forms of light therapy were proposed.
During the last 60 years, laser treatment techniques evolved meteorically. The laser now serves in many fields, both in industry and in medicine. The word 'laser' is an acronym of Light Amplification by Stimulated Emission of Radiation. The laser is an electromagnetic monochromatic coherent wave with fixed wavelength, and as such, it has good penetration ability and is able to transfer a large amount of energy to a very narrow beam. The laser use is done by a single beam or a cluster of beams. Repeated studies discovers that in wavelengths of f 600 to 900nm and intensity of 1-1000m W, not only that the laser wave does not cause damages, but it actually has a beneficial effect on the tissues and on the cells function on the systemic level. The term Low Level Laser Therapy (LLLT) is the accepted term to differentiate between soft lasers, which serve for medical treatments, and 'hard laser', which is used in several kinds of surgeries. The accepted terminology is therefore, soft laser, LLLT, cold laser, or low level laser.
The laser effect is done on the tissue level by lowering the inflammation factors in the injured area, such as prostaglandin-endoprexide syntheses 2, interleukin 1-beta, tumor necrosis and factor-alfa. This lowers the entrance of the neutrophil granulocytes, oxidative stress, swelling and hemorrhage. On the citoplasmatic cellular level, the ADP effect on the mitochondrion, and therefore changes the cellular homeostasis, activates enzymes and increases ATP production.

The device
B-cure Laser, an Israeli Company, managed to expand the width of the beam. This innovation enables to illuminate an area of about 4.5 square centimeters in a 808nm monochromatic coherent wave length and in 250m W intensity.
The soft tissue effective penetration depth of laser with such intensity is up to 4 centimeter under skin layer. The energy can reach up to 6 centimeters, though the effectiveness in such depth is low. There are no known side effects. There are, as well, no known damages when treating above the recommended therapeutic window. The only limitation: recommended not to point directly to the eyes and avoid direct eye contact.

In light of the background presented above, the many researches that were done on the subject in the scholarly literature in the last 20 years, as well as my acquaintance with B-cure Laser and the medical needs of IDF disabled veterans, I would like to detail bellow the recommended indications.

Recommended Indications for Treating IDF Disabled Veterans:

Treating Tendinitis

For Example:

Levator scapula Tendinitis, Bicipital tendinitis, DeQuervain's Tendinitis, Trigger finger, Pez ancerinus Bursitis, Trochanteric Bursitis (in skinny people), runners knee (Biceps femoris tendinitis), Junper's knee (Patellar Tendon Tendinitis), Achiles tendinitis, Plantar Fasceitis.

Treating Small Joints Arthritis

For Example:

Temporomandibular joint, shoulder pain, finger joints, wrist joints, pains after fracture healing, non-connecting fractures in carpal bones and pains due to osteoporosis in feet joints.

Treating Hard-to-heal Wounds

Such as diabetic wounds and neuropathic pains.

Treating Acute Injuries

Painful and absorbed hematoma, injuries and intramuscular hematoma.

Periodontal Healing

After periodontal surgeries, dental extractions and dental stitching. (In these cases, it is recommended to use high-potency laser).

Treating Nonspecific Back and Neck Pains*

Applying to trigger points, sore muscles and pain points.

It is important to mention that laser treatment does not come instead of medical diagnosis and treatment by a licensed physician, tough it can, with no doubt, serve as a symptomatic treatment in many cases of musculoskeletal pains, as well as adjunctive therapy and prophylaxis.

Treating Bio-mechanical Chronic Injuries

In some cases injuries can cause deformations, traumas and biomechanical damages which lead to chronic disorders. These disorders cause pain due to aberrant muscle activation, which in turn cause continuous load on fixed points and chronic pains. Patients, who suffer from these kinds of problems, tend to consume pain killers and other prescribed drugs over long periods of time, which can cause temporary or permanent damage. In these cases it is possible to use the soft laser each time there is an exacerbation of the pain, as well using it as prophylaxis and preservative treatment between exacerbations.

Summery:

According to all the above, and according to the EBM criteria, I believe it will be advisable to use this kind of treatment as an alternative to analgesic symptomatic treatment that is given currently given to IDF disabled veteran, according to the indications above

Sincerely,
Dr. Hagay Amir
I.D number: 055976021

Dr. Dolinsky Rina, Deputy Director of the 6th Department of Internal Medicine,
Western Galilee Hospital, Nahariya

14.08.2013

To Whom It May Concern,

I have began using the B Cure Laser device about a year ago, in an attempt to ease neuropathic pains in my daughter's leg. Shortly thereafter, I have purchased an additional device for my own personal use. The device was intended for muscle pains, lower back and neck pain.

Additionally, I have used the device for easing muscle pain after prolonged sitting, and to treat acne, for my younger daughter. I also have used the device for speeding up surface wound healing.

After an extended teeth treatment, the device was used for shortening the recovery period of the gums, with great success.

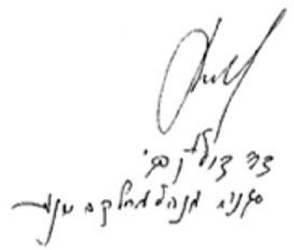
The device was also used for easing a blocked nose and throat pain. Following the period of time when I and my family members have used the device with obvious positive results I recommended an ALS patient on a permanent respirator to also use the device.

This patient has suffered from muscle pains due to prolonged sitting or lying down sessions, and following his beginning to use the device, the amount of his pain relieving medication was significantly reduced.

In addition, this patient has used the device successfully to relieve the appearance of pressure ulcers, and locations of festering skin infections.

Following the positive results that were obtained with the use of this device, this patient's parents recommended the ALS patients' association of Israel to use this device for other patients.

Dr . Dolinsky



4. Doctors' Reviews

07.08.2013

Subject: B Cure Laser

To Whom it may concern,

My name is Dr. Shebshewitz Victor. A Pain Doctor,in a Pain Clinic, Rambam Hospital.
I have been using the B Cure Laser for 3 years, continuously, in the Pain Clinic.
Its use has been conducted in the following groups of patients:

Joint pain – osteoarthritis:

about 30 patients. They were treated with the device once a day, as needed , for up to 10 minutes.
After 5-6 sessions the patients experiences a significant relief and improvement.
Out of the 50 patients – 75% have reported a relief and an improvement.

Neck and back pain

about 50 people were treated with the device in accordance with the protocol.
The patients have reported a relief and an improvement of the pain.
75% of the patients have experienced a relief and an improvement.

Headaches

20 people were treated with the B Cure laser.
After 5 treatments in 70% of the cases there was an improvement.

Neuropathic pains in diabetics(PNP)

between 15 and 20 patients.
After about 10 sessions, 50% reported a relief and an improvement in the pain.

Hard to heal wounds - mainly in the leg area.

15 people. After a month of treatment, there was a recognizable improvement and healing in the wound by 50% of the patients.
In some of the patients the wound has closed completely.
In my experience, the B Cure Laser device is effective and there is room for using it in pain and wound treatment.

Dr. Victor Shebshewitz
P.N. 27175
The Pain Treatment Institute,
Rambam Medical Center

5. Thank you letters from patients

Chadig'a Muchsan -
Osteomyelitis - a closure of a stump and treatment of an ulcer with B-Cure Laser

Hey Mickey.

First of all I would like to thank you for the device.

I was hospitalized on 07-7-13 because of an abscess in the right stump. The first surgery was performed on the 12-7-13, opening of the stump for the purpose of cleaning out the abscess. The surgery was not successful, and I encountered many problems in my stump during my hospitalization at the Bnei Tzion Hospital. Between the first surgery and the second there was an interval of a few hours, for the purpose of an additional debridement and an unsuccessful attempt to close the stump. Between the dates of 4-8-13 and 11-8-13 I underwent the third and the fourth surgeries, again for the purpose of cleaning out the stump and closing it, and again, they were unsuccessful!!!

After 4 difficult and despairing times at the surgery, I decided to request the doctors to cut a 1,5 cm off the bone, and that was the 5th and last surgery, and it was partially successful. I was released to my home, with my stump relatively open, as I have seen in the photos, and actually, from that time I have been using the B Cure Laser device. On 27-8-13, after a few weeks, I began to see a huge improvement in the stump. It continued to close rapidly, comparing to the previous surgeries I had undergone, and with all the previous failed attempts to close the stump. Because of my illness, as you know, it takes a very long time to heal wounds.

In the beginning I would use the B Cure Laser, once to twice a day. In the beginning for 5-10 minutes, directed at the suture line, which is where the problem of closing up started from. After a few days I continued onto 3 times, for a period of time between 15 to 20 minutes, and I always dedicated 5-7 minutes to the suture line. With the great improvement of the stump closing up completely, without a drop of discharge! Even my surgeons were surprised by the fast closure of the stump! And after that I treated the stump with movement, and not only on the suture line. I even had a wound on my right knee, and there I also treated it, and slowly-slowly, maybe after a month, there was no longer a wound there! It was incredible, because it usually takes months for my knee wounds to heal, and sometimes it even takes years.

In the beginning I have been using the B Cure Laser, once or twice a day, In the beginning 5-10 minutes directed at the suture line.

And this is, obviously, thanks to you.

During the treatment with the B Cure Laser I had some aches and pains, very different from other pains that I usually feel in the stump. An entirely different pain.

I have treated it only with the B Cure Laser, without any additional treatment, only dry bandages to protect the stump.

Sincerely,
Chadig'a Muchsan

Chadig'a Muchsan - A closure of a stump and treatment of an ulcer with B-Cure Laser

4-11 August 2013

The state of the stump after 4 surgeries, the stump does not manage to heal and the ulcer is developing.

stump

ulcer

25th September 2013

The state of the stump after about 5 weeks of treatment with B-Cure Laser and dry bandages only.

8th October 2013

The state of the stump after about 8 weeks of treatment with B-Cure Laser and dry bandages only.

Yaakov Lerner

06/20/2013

To: Erica Carmel Ltd.

Re: B-Cure Laser Device

I hereby declare I use the medical device B-Cure Laser, which I purchased 3 years ago from Erica Carmel Company.

I hereby confirm that this device prevented the leg amputation surgery, after all other medical treatments in the hospital failed.

I started using the device since I had no other choice and after a short period of three months, a diabetic wound, 8 centimeters in diameter, was healed.

Today I am a happy human being. I am able to wake like any other person, thanks to this device, which became my loyal and trusted friends, helping me dealing with all kind of serious medical problems such as: toothache, back pain, leg muscles pain, pressure sores, edema in my legs, fingers and ears and others.

I continue to use the device as preventive treatment to this very day. I am very pleased with the results, I strongly recommend it for cases which cannot be treated by regular medicine.

Thank you for all the help and the caring for my medical condition.

Sincerely and respectfully yours,
Yaakov Lerner
Misgav, Dov 20 Shorer Valley

June 2011

August 2011

September 2011

MedRefDFU-EN-01 November 2017

B-Cure Laser Pro

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