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EVALUATION OF THE CERALAS D15 DIODE LASER AS AN ADJUNCT TOOL FOR WOUND CARE: A PILOT STUDY

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SUMMARY

The Ceralas D15 diode laser is a GaAlAs diode laser that delivers up to 15 watts of optical power at 980 nm using a quartz fiber delivery system. The purpose of this study was to evaluate the Ceralas D15 laser as an adjunct tool in wound care. Ulcers were treated with the laser once every two weeks for a minimum of four treatments. During this time, the patients continued their previously-prescribed treatment. The change in area of the ulcers and the change in bacterial count were evaluated following laser treatment. The laser appeared to enhance wound healing, as indicated by a decrease in ulcer size, while decreasing the bacterial count at the site of the wound. In addition, the patients were highly satisfied with the use of the laser, and in general, had no discomfort during treatment. The results of this preliminary investigation are promising, and encourage further study.

Keywords: diode laser, biostimulation, wound healing, bacterial count

INTRODUCTION

Approximately 11 million Americans are inflicted with diagnosed diabetes and there are approximately 60,025 new cases diagnosed every year (1). The leading cause of hospitalization for diabetes mellitus is foot ulceration with infection, and it is estimated that approximately 15% of all diabetics will develop a foot or leg ulceration (2). Fifty percent of all nontraumatic amputations in the United States occur in diabetics. In 1994, diabetes-related lower extremity amputations accounted for almost 100,000 days of hospital stay and the average length of hospitalization approached almost two weeks. One of the primary factors leading to amputation was wound healing failure. The vast majority of these amputations were attributed to skin ulcerations (2).

The American Diabetes Association estimates that one-half of the amputations are preventable. It is estimated that a net savings of 24 to 30 thousand dollars can be saved for each amputation prevented (3). In addition to the associated medical expenses, amputation and disability associated with prolonged wound healing cause both personal financial and psychological consequences. The annual cost associated with foot disease in diabetics is estimated to be more than one billion dollars. This estimate does not reflect physician fees, rehabilitation costs, prostheses, disability payments or time lost from work.

Amputation of one limb predisposes a patient to subsequent amputation on the same or opposite limb within five years at a rate as high as 50%, and the five-year mortality rate following lower extremity amputations may range as high as 68% (4). It would seem that a non-invasive and non-destructive method to promote wound healing by stimulation of the patient's own tissues, irrespective of the underlying cause of the ulcer, could greatly reduce unnecessary amputation, health-care costs and personal loss in both time and income for the affected patients.

Lasers have demonstrated beneficial effects on wound healing in a variety of

experimental and clinical conditions, and have been shown to produce non-destructive effects on tissues at the cellular level (5,6). Studies, both in vitro and vivo, have determined that several different types of lasers produce beneficial biological laser effects. These lasers include the helium-neon (HeNe), argon (Ar), yttrium-aluminum-garnet (YAG), gallium-arsenide (GaAs) and gallium-aluminum-arsenide (GaAlAs) lasers. The laser effect, referred to as biostimulation or photostimulation, results in an increase in cellular respiratory mechanisms (5), ATP synthesis (5), DNA and RNA synthesis (5,7), cell proliferation (8,9), collagen synthesis (8,10-14), and fibroblastic reaction (11,15). Biostimulation has also been shown to result in photochemical stimulation of atoms or molecules (5), release of cytokines (6,16), stimulation of ascorbic acid utilization by cells (7), modulation of the production of growth factors (including transforming growth factor and platelet-derived growth factors) (17, 18), and the development of new blood vessels (11,15,17). A decrease in time required for experimental and clinical wound healing has also been reported (8,16,19-24). Laser stimulation does not appear to alter the inflammatory effect of monocytes and endothelial cells in vitro; cells that are also important for good wound healing (25).

Recent studies that utilized lasers for the treatment of diabetic foot complications have demonstrated increased rates of wound healing. Using a double-blind, placebo-controlled study, A. Schindl and others have documented thermo graphically that low-level laser treatment may induce a positive effect in conditions of reduced microcirculation. The measured increase in temperature was attributed to increased skin microcirculation. This laser-induced effect was speculated to result by stimulation and proliferation of endothelial cells that may cause the release of transmitted substances, thus resulting in the opening of free existing small vessels (19). In a subsequent study, A. Schindl et. al. reported on a case of complete wound healing in a patient with a diabetic foot ulcer after 16 laser treatments that were applied over a four-week period. This study suggested that laser therapy might prove useful in the management of diabetic neuropathic foot ulcers and constitute an alternate treatment that is free of side effects (20). Yet another study by M. Schindl, of the same study group, reported that laser therapy was valuable in reducing the healing time of various wounds and ulcers including neuropathic and vascular diabetic foot ulcers, ulcers due to arterial insufficiency and autoimmune disease, and skin defects secondary to radiation therapy (21).

The results presented by these initial findings indicate that laser therapy has the potential to be a useful and desirable method in the management of diabetic foot ulcerations. Unlike current forms of one therapy, including the use of recombinant growth factors, the resulting photostimulation of laser therapy will stimulate the patient's own cells and tissues to participate in the wound healing process. Recent work using a diabetic animal model has reported that laser therapy as a monotherapy was found to be more effective than topical fibroblast growth factor and combined laser therapy with fibroblast growth factor in stimulating wound healing (17).

The purpose of this study was to evaluate the efficacy of using the Ceralas D15 diode laser as an adjunct tool for wound care. The effect of diode laser therapy on wound size and bacterial count at the wound site was examined. In addition, the patient’s level

of satisfaction with laser treatment was evaluated. The results of this study should give some insight into the effect of the diode laser on healing wounds of the lower leg and foot.

MATERIALS AND METHODS

Materials

The Ceralas D15 diode laser (CeramOptec, Inc., East Longmeadow, MA) was used in this study to induce photostimulation. The Ceralas laser is a Gallium-Aluminum-Arsenide (GaAlAs) diode laser, which delivers up to 15 Watts of optical power at a wavelength of 980 nm. The laser energy was applied via a quartz fiber optic delivery system.

Methods

Subjects were selected from patients with wounds that were being treated at the Wade Park or Brecksville divisions of the Cleveland VA Medical Center. Patients with all types of ulcers, including venous, ischemic, neurotrophic and traumatic wounds, were eligible for the study. Patients with wounds that penetrated the epidermis, dermis and deep fascia were included, while those with wounds that involved active infection, deep abscess, osteomyelitis, and exposure of the tendon, capsule or bony structures were excluded from the study. The study protocol was reviewed and approved by the Institutional Review Boards of the Ohio College of Podiatric Medicine and the Cleveland VA Medical Center to ensure that the rights and safety of the patients were protected.

All subjects were required to receive laser treatment at the initial visit and at a minimum of three follow-up visits. The time between visits was generally two weeks. Due to uncontrollable circumstances, however, the time between follow-ups was occasionally three weeks. Patients who did not report for follow-up treatments within three weeks were removed from the study.

During each laser treatment, the wound was debrided with a scalpel. Initial debridement was more effective with a scalpel, due to the excessive amounts of hyperkeratotic and fibrous tissues around the ulcer. The ulcer was then measured for maximum length and width, and examined for changes in appearance. The laser power was set to 5 watts, and the laser energy was applied to the wound in a criss-cross pattern to ensure complete exposure of the ulcerative area. After laser treatment, a photograph was taken of the ulcers and the patients continued with their previously-prescribed treatments, including medication and dressings. Finally, the patient was asked to fill out the Patient Questionnaire, in order to evaluate patient satisfaction.

To analyze wound healing, the percent change in area from the initial visit was calculated for each follow-up visit, according to equation 1:

(1) $\%\Delta A_i = ((A_{FUx} - A_i)/A_i) \times 100$

where A_{Fux} is the area of the ulcer at follow-up visit #x, and A_i is the area of the ulcer at the initial visit. According to equation 1, an increase in the area of the ulcer, in comparison to that at the initial visit, will result in a positive percent change in area. Conversely, a decrease in the area of the ulcer, in comparison to that at the initial visit, will result in a negative percent change in area. (*read this)

The effect of the diode laser on the number of bacterial organisms present on the wound was evaluated, using ulcers from the patients who were treated at the Brecksville facility. In addition to the treatment described above, bacterial culture swabs were taken from the base and wall of the ulcers immediately before and immediately after laser treatment. The cultures were then grown on Brain-Heart Infusion (BHI) agar at 35 °C for 36 hours. After the incubation period, the culture dishes were analyzed to determine if there was an increase or decrease in bacteria following laser treatment. Where applicable, counts of the colonies were made, and the percent change in bacterial count was calculated, according to equation 2:

(2) $\%\Delta N = ((N_A - N_B)/N_B) \times 100$

where N_A is the number of microbial colonies present after laser treatment and N_B is the number of microbial colonies present before laser treatment. According to equation 2, an increase in the number of bacteria after laser treatment, compared to that before the treatment, will result in a positive percent change in bacterial count. Conversely, a decrease in the number of bacteria present after treatment will result in a negative percent change in bacterial count.

Statistical analysis was conducted, where applicable. The two-tailed student's t-test was used to determine statistical significance.

RESULTS

A total of 19 ulcers from 16 patients were included in the study. All of the 16 patients who completed the study were males. The age of the patients ranged from 45 to 81 years, with an average of 62.8 years. Twelve of the ulcers were from diabetic patients, while seven were from non-diabetic patients. The length of time the ulcers were present prior to initiation of the laser treatments ranged from one week to greater than 10 years, with a median of eight months.

Of the 19 ulcers, seven (or 36.8%) were completely healed during laser treatment. This included three neurotrophic ulcers, two venous ulcers, and two traumatic ulcers. Six of the seven healed ulcers were from patients diagnosed with diabetes. The average number of treatments required to close the ulcers was 4.1. Thus, the ulcers were closed after an average of approximately eight weeks, or two months. The length of time these seven ulcers were present prior to initiation of laser treatment ranged from 1.5 months to 27 months, with a median of five months.

Percent Change in Area

The results for the percent change in area from the initial visit, shown in Figure 1, indicated that at the first follow-up visit, the area of the ulcers had increased by 24.0% from the initial visit. At the second follow-up visit, the ulcers decreased by an average of 17.5%, compared to the original area of the ulcers. At the third follow-up visit, the area of the ulcers had decreased by 24.0% from the initial visit. Finally, at the fourth follow-up visit, the ulcers had decreased by 9.4%, compared to the original area of the ulcers.

The data for percent change in area from initial visit was compared between diabetic and non-diabetic patients, as seen in Figure 1. Between the initial and first follow-up visits, the area of the ulcers increased by 17.1% for diabetic patients, compared to an increase of 32.9% for non-diabetic patients. This difference was not significant ($p=.445$). At the second follow-up visit, the area of the ulcers decreased by 23.0% from the initial visit for the diabetic patients, and by 9.0% for the non-diabetic patients. Again, this difference was not significant ($p=.501$). At the third follow-up visit, the area of the ulcers decreased by 35.6% from the initial area for diabetic patients, and by 9.1% for non-diabetic patients. This difference was not significant ($p=.346$). Finally, at the fourth follow-up visit, the area of the wounds decreased by 18.3% from the original area for diabetic patients, and increased by 0.9% for non-diabetic patients. Again, this difference was not significant ($p=.561$).

Bacterial Culture Analysis

Eleven patients, with a total of 13 wounds, participated in the analysis of the effect of the diode laser on bacterial counts. Thirty of 34 cultures taken from the wall of the ulcers, or 88.2%, indicated a decrease in bacterial count following laser treatment. Twenty-seven of 35 cultures taken from the base of the ulcers, or 77.1%, also indicated a decrease in bacterial count after laser treatment. One of the 35 cultures taken from the base, or 2.9%, showed no change in bacterial count after treatment with the laser.

Twenty-two of the cultures obtained from the wall of the ulcers and 23 of the cultures taken from the base of the ulcers were used to count colonies before and after laser treatment. The results, shown in Figure 2, indicated that prior to laser treatment, the bacterial count on the wall of the ulcers averaged 78,232.3. This number decreased to an average of 40,452.3 after treatment with the laser. The difference was not statistically significant ($p=.261$). The results from the base of the ulcers indicated that the bacterial count decreased from an average of 46,197.0 before laser treatment to an average of 30,569.6 after treatment. Again, this difference was not significant ($p=.516$).

The average percent change in bacterial count after laser treatment indicated that the bacterial count on the wall of the ulcer decreased by an average of 45.9% after treatment with the laser. Similarly, the bacterial count on the base of the ulcer decreased by an average of 47.3% after treatment with the laser. The difference in percent change between the wall and the base of the ulcer was not significant ($p=.938$).

Patient Satisfaction

The results from the patient questionnaire are shown in Table 1. All patient responses, including those from patients who were later removed from the study due to infection or missed follow-ups, were included in the analysis. Twenty-seven patients responded for a total of 85 completed questionnaires. Pain was reported during or after 8.2% of the treatments, while swelling was a complaint in 11.8% of the responses. Improvement after treatment was noted in 68.2% of the responses, while 75.3% of the responses rated the treatment as better than that which they were receiving prior to enrollment in the study. The smell of smoke during treatment was reported in 9.4% of the responses. Only 3.5% of the responses expressed concern about treatment with the laser, and 100% of the responses indicated that the patient would request laser treatment again.

The responses of the patients who completed a minimum of four laser treatments (initial and three follow-up visits) were analyzed further, in order to evaluate patient satisfaction over the course of the treatment. Table 2 shows the responses at each follow-up visit to the question of noticeable improvement after laser treatment. At the first follow-up visit, 72.2% of the patients reported an observed improvement after laser treatment. The number of patients reporting an improvement in their ulcers increased to 76.5% at the second follow-up visit, and to 87.5% at the third and fourth follow-up visits.

DISCUSSION

Wound Healing

Seven of the 19 ulcers that were included in the study were completely healed during the course of treatment. The ulcers that did close during the course of the study were present for a range of 1.5 months to 27 months prior to initiation of the laser treatment, without significant healing, in spite of active treatment protocols. The fact that these ulcers were completely healed within an average of two months suggests that the laser therapy does enhance wound healing.

The results of the percent change in area indicate that, after the initial treatment with the laser, the size of the ulcers increased. However, after the second treatment with the laser, the size of the ulcers was smaller than the original size of the original ulcer. This decrease in size of the ulcer, compared to the initial size of the ulcer, continued at the third follow-up visit. At the fourth follow-up visit, the percent change in area from the initial visit, while still less than the original size of the ulcer, was less than at the previous follow-up visit. These trends are observed in both diabetic and non-diabetic patients, but are more apparent in the diabetic patients. The findings suggest that the diode laser does enhance wound healing, but the effect might be most significant during the first few treatments.

Patient compliance may be a cause of variation in the results. Subjects that are seen at the Brecksville VA Medical Center are in-house patients, and thus, tend to be

more compliant than the outpatient participants from the Wade Park VA Medical Center. This is a variable that is extremely difficult to control in clinical studies. Much of the clinical research on the effects of lasers on wound healing in humans has been poorly controlled or not controlled at all. Despite the limitations of human clinical studies, there is a great amount of literature that suggests that lasers can cause biostimulation of wound healing (24).

Lasers provide low energy stimulation of tissues, resulting in increased cellular activity during wound healing (26). The chemical and metabolic changes that occur within the cells during laser biostimulation are poorly understood (27). Mechanisms of action include stimulation of ascorbate uptake by cells, stimulation of photoreceptors in the mitochondrial respiratory chain, changes in cellular ATP or cAMP levels and cell membrane stabilization (8). Fibroblast proliferation, collagen synthesis, macrophage stimulation, and a greater rate of extracellular matrix production are some aspects of wound healing that are reportedly affected in vitro (13,28). According to Karu, biostimulation is not always possible. The magnitude of the biostimulation effect depends on the physiological state of the cell before irradiation (5).

Bacterial Culture Analysis

The results from the bacterial culture study indicate that, in general, the bacterial count decreases after laser treatment. This was observed on both the wall and the base of the ulcers. While these changes were not significant, due to the large range in the number of colonies present on the different ulcers, there is a definite trend towards a decrease in bacterial count after laser treatment. As expected, there was no significant difference in the percent decrease in bacterial count between the wall and the base of the ulcers.

The results from the bacterial culture study also suggest that the effect of the laser on bacterial count is temporary. However, with more frequent laser treatments, as suggested above, the use of the laser should decrease bacterial counts throughout the course of treatment. Additional studies are needed to determine the effect of the laser on specific types of bacteria.

Robson demonstrated that wounds that contain less than 10^5 bacterial microorganisms per gram of tissue in all zones have a higher rate of healing (29). The reduction in bacteria potentially will result in a decreased infection rate secondary to tissue invasion by surface and colonizing bacteria, which may, in diabetics with immune compromise, result in limb threatening infections. Thus, the effect of laser treatment may reduce the use of costly antibiotic therapy and promote wound healing by decreasing the bacterial count.

Patient Responses

The results from the patient questionnaires suggest that the patients experience very little pain and/or swelling during and after laser treatment. In most instances, pain

was reported by the first few patients in the study. At first, the laser was applied at a power of 8 Watts. This seemed to cause discomfort and burning sensation in the patient. As a result, the power was decreased to 5 Watts for the remainder of the study. Pain was also reported if the tip of the optical fiber made contact with the wound or adjacent skin.

The patient questionnaire also revealed that a small number of patients smelled smoke during treatment. However, it should be noted that the physician and others in the room at the time of treatment did not smell or see smoke during any of the treatments.

Only a small minority of the responses (3.5%) expressed concerns by the patient about being treated with a laser. Most of the concerns were in regard to long-term effects of the laser or fear of pain, and the concerns were allayed by the physician. The majority of the responses (68.2%) indicated that the patient noticed an improvement in their ulcers, and all of the responses (100%) indicated that the patient would request laser treatment again for the ulcers.

The responses of the patients who received a minimum of four laser treatments (initial visit and three follow-up visits) were evaluated over the course of their treatment. The percentage of responses that noted an improvement in healing after laser treatment increased at the second follow-up visit, and again at the third follow-up visit. The percentage then remained constant at the fourth follow-up visit. This indicates that the patients were increasingly satisfied with the results of the laser as their treatments progressed. In general, the responses indicate that the large majority of patients were satisfied and pleased with the results of the laser treatment.

CONCLUSIONS

The results from this preliminary evaluation of the effectiveness of the Ceralas D15 diode laser as an adjunct tool in wound healing are very encouraging. The laser appears to enhance wound healing, while decreasing the bacterial count at the site of the wound. No significant difference in wound healing following laser treatment was discovered between diabetic and non-diabetic patients. The patients were highly satisfied with the use of the laser, and in general, had no discomfort during treatment. The physicians who used the laser also praised the ease of use and the effectiveness on wound healing. Additional studies are ongoing to evaluate the effect of the laser with increased frequency of treatments, and to further evaluate the effect of the laser on wound healing in diabetic versus non-diabetic patients.

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TABLES

Table 1

Analysis of Patient Questionnaire (n=85)

	Pain	Swelling	Smell Smoke	Concerns	Improvement	Treatment Again
Yes	7 (8.2%)	10 (11.8%)	8 (9.4%)	3 (3.5%)	58 (68.2%)	85 (100.0%)
No	78 (91.8%)	75 (88.2%)	77 (90.6%)	82 (96.5%)	27 (31.8%)	0 (0.0%)

Table 2

Patient Responses: Did you Notice Improvement After Treatment?

	Follow-Up 1	Follow-Up 2	Follow-Up 3	Follow-Up 4
Yes	13 (72.2%)	13 (76.5%)	14 (87.5%)	7 (87.5%)
No	5 (27.8%)	4 (23.5%)	2 (12.5%)	1 (12.5%)

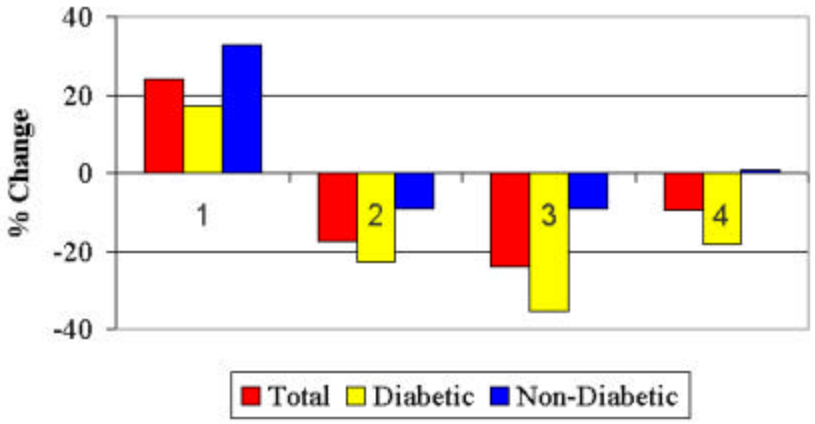

Figure 1: Percent change in area from the initial visit at follow-up visits #1-4

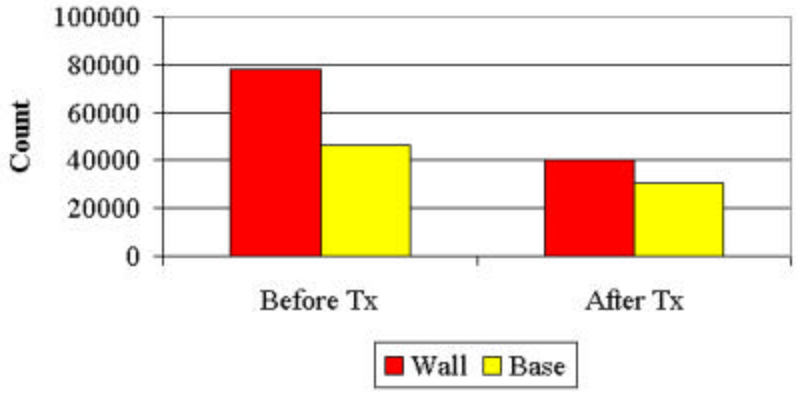

Figure 2: Bacterial counts before and after laser treatments