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Comparison of Energy Spread Homogeneity in Automated and Manual Class 4 Laser Therapy

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Research Article

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ABSTRACT

BACKGROUND: The application of Class IV laser therapies in the last two decades is a continuously growing physical modality based on its bio stimulation and pain relief effects, while simultaneously being a non-invasive therapy. Due to its high power output which can provide thermic effects and shorten therapy time, as well as long wavelength which allows for superior penetration into deep structures when compared lowing level laser therapies, makes Class IV laser a preferred laser therapy option. As technology trends change and advance the demand for automated lasers coming out onto the market is expanding. It is of vital importance that the reliability of such automated laser systems meet or surpass certain standards and expectations of reliability when compared to manual laser therapy applications.

OBJECTIVE: The aim of this study was to evaluate the homogeneity of the spread of energy delivered by the manual hand piece and automated scanning system applications to the back area of 100 cm^2 with a maximal power of 30W and single wavelength of 1064 nm.

METHODS: 70 patients were assigned into two groups based on their skin types according to the Fitzpatrick scale. Group I consisted of skin type II and III, while Group II consisted of skin type IV and V. Treatment methods were the same for both groups, where each patient received an initial treatment with the manual applicator and one week later received treatment with the automated applicator. A Fluke infrared camera was used to obtain thermal images and values of both treatment methods for (qualitative and quantitative) comparison.

RESULTS: Based on the thermal images evaluation, mean difference in temperature for each application, and homogeneity coefficient evaluation, a significant ($p>0.01$) difference was observed between the manual application and automatic application for both skin type groups, in which the automated application provided a more homogeneous spread of energy compared to the manual application using the hand piece. Moreover, there was no significant difference ($p>0.01$) for either application on different skin type groups.

CONCLUSION: Class IV automated laser application, with a single 1064 nm wavelength and power of up to 30 W was found to provide a greater homogenous spread of energy in relation to the Class IV manual application.

INTRODUCTION

Laser therapy is a physical modality which uses laser light radiation for biostimulation and pain relief targeted into deep lying tissues. In the past devices with a maximal power of 500 mW (Class III) were used for laser therapy [1,2]. Due to technological advancements and changing technical trends, a higher amount of energy over 1W and up to 30W can be delivered to the patient within a second when using high intensity lasers (Class IV) [3]. This poses many benefits for the therapist and patient as higher power output can provide a thermic effect for acute, but strong thermic effect for chronic conditions, as well as decrease therapy time since energy can be delivered more effectively to the treatment area [4]. Laser irradiation parameters such as wavelength and size of the application spot have shown to influence the penetration into the human tissue [4,5]. Spectral dependency of the wavelength into the penetration depth was the subject of previous investigations and concludes that wavelengths above 1000 nm reach deeper penetration. This is the main driving factor of using a single wavelength of 1064 nm when applying laser therapy treatment.

Reducing the therapeutic laser spot will increase the areal power density of the laser, in turn decreasing laser absorption in the skin and improving the reach for deeper penetration [6]. Despite this benefit, control of the small spot can be difficult and could affect the energy spread in the targeted area, especially on the areas over 100 cm^2.

Different types of Class IV laser delivery can be used for the application of laser therapy. Manual application using a hand piece is the most common type of delivery currently available to medical providers. It consists of using a probe with the laser output which is usually in a defined distance position from the patient's skin and needs to be delivered dynamically to prevent uncomfortable heat perception. Moreover, larger body parts tend to be more difficult to treat effectively due to their size and the application consistency required. Based on this constraint, the implementation of an automatic application for laser therapy seems favorable, as it will be better able to treat large body areas, save operator's time and eliminate fatigue compared to manual laser therapy application.

Recently, automated Class IV lasers were introduced on the market with features such as an IR camera to control for energy spread and different mechanisms on how to make to make the laser light beam move.

To better understand these different application systems for Class IV laser therapy, this study aimed to evaluate the homogeneity of the energy spread delivered by both manual and automatic applications.

MATERIALS AND METHODS

Inclusion Criteria

Inclusion criteria consisted of skin types II and III for the first group, skin types IV or V for the second group.

Exclusion Criteria

Patients were excluded from the study if they had central or peripheral neuropathy, exhibited open skin lesions, were pregnant, experienced acute or sub-acute inflammation and/or had a malignant (cancerous) tumor.

Study Design

The study was designed as a comparative trial. A total of 70 patients were split into two groups according to their skin types.

Ethical Standards

All patients were given a full explanation of the treatment protocol and written informed consent was obtained. Furthermore, the treatment method was conformed with the ethical guidelines of the 1975 Declaration of Helsinki adopted by the General Assembly of the World Medical Association (1997-2000) and by Convention on Human Rights and Biomedicine of the Council of Europe (1997) [6,7].

Data Collection

In order to evaluate patient's skin type the Fitzpatrick scale was used [8].

Therapy Device

A semi-conductive Class IV Laser with the manual hand piece and automated scanning system applicator (BTL Industries Ltd) consisting of a maximal power of 30 W and 1064 nm wavelength was used.

Therapy Procedure: General

Constant ambient temperature of 21˚C was kept in the laser operatory room for a consistent therapy environment. Patients rested approximately 10 minutes in the operatory room to adapt to the temperature. Both the patients and operator wore protective laser safety eyewear for eye protection. Applications were common for both groups; laser was applied on the patients back while in a prone position situated on a treatment table. The defined treatment area was marked on the patient's skin (using a highlighter) for easier post-evaluation. Laser application treatment was performed two separate times. The first intervention applied the manual laser therapy application. The second applied the automated application, which was performed 7 days following the manual application as to avoid lasting metabolic effects of the first manual laser intervention as to avoid misinterpreted data and mimic the initial baseline state.

Therapy Procedure with Manual Application

Manual laser delivery was performed by the hand piece applicator of the BTL-6000 High Intensity Laser device. The size of the therapeutic spot was adjusted by the optical attachment and set to 10 mm in diameter. Therapy was applied in a dynamic scanning motion with the constant speed of 4 cm/s with a continuous emission.

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Therapy Procedure with Automated Application

Automated application was performed by the accessory Scanning System. Constant spot size of 10 mm diameter was used. Like the manual application, the same dynamic scanning motion application and constant speed was used. The distance between the patients back and the scanning system was a constant 20 cm. All patients held a laser stop emergency button during the entire automatic application in case of any sudden major discomfort.

Therapy Parameters

Laser therapy was applied on an area of 100 cm^2 (10 cm x 10 cm) on the patients back using the 10 mm spot size for both applicators. A fixed distance of 3 cm for the hand piece and 20 cm for the Scanning System was used between the patient and laser output. A fixed dosage of 70J/cm^2 was delivered by the continuous emission with power ranging from 10 W to 15 W according to patients thermal perception.

Measurement Apparatus

Thermal image evaluation data was captured by the thermal camera Fluke model TI32 (Fluke Corporation) with a resolution of 240x320 px. All thermal images were captured in degrees Celsius in the range of 28-43˚C. Emissivity coefficient of 0.98 was used.

Evaluation Methods

Three different types of homogeneity evaluations were used in this study. The first consisted of a visual homogeneity evaluation of the temperature spread in the thermal images. For the second method temperature values from the therapeutic areas were kept, the difference from the average temperature of the treated areas were calculated and the percentage of the difference in values were visualized on the range -4˚C to 4˚C with 0.4˚C increments. The last evaluation method applied a Homogeneity Coefficient (HC), which was defined as the average percentage for every single difference represented by the difference values with the higher percentage than 3%. Mathematical software GNU Octave (version 5.1.0) was used to evaluate the thermal data.

Statistical Analysis

Each group was analyzed by the Mann-Whitney U-test to compare the difference between automated and manual application. Differences of the HC between the skin types groups for the same application were examined. The level of statistical significance was set as $p<0.01$.

RESULTS

A total of 70 patients were split into two groups based on their skin type. The first group of 35 patients was classified as skin types II and III, whereas the second group of 35 patients was classified as skin types IV and V. Both of these groups did not report any side effects or problems following any of the treatments. Once we obtained thermic data on the treated patients from both the manual and automated applications using a thermal camera, we were able to evaluate and extrapolate further information to better understand the homogeneous spread of energy of both applications.

Thermal Images Evaluation

Homogeneity evaluation of the thermal images was performed. The main difference between the automated and manual application were visible edges of the therapeutic area for both skin type groups **(Figure 1)**. The central section of the therapeutic area shows signs of increased homogeneity for the automatic application, whereas for the manual application we observe a more varied and less uniform distribution of energy.

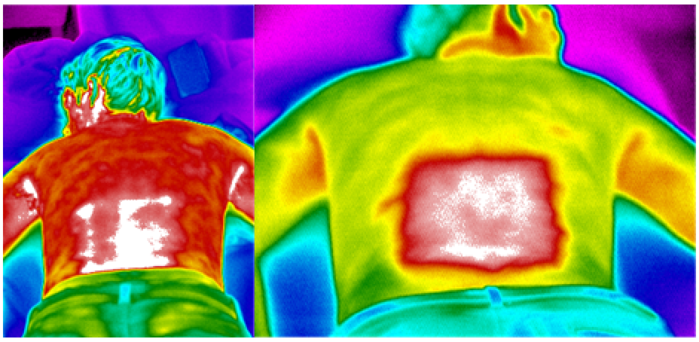

Figure 1. Thermal images for manual (left) and automated (right) application for skin type II.

Difference in Temperature Values and Area Percentage

Difference between the mean temperature in the therapeutic areas and individual pixels from the thermal camera images were calculated for both groups and applications. Furthermore, percentage distribution was plotted. Energy spread for the manual application shown in **Figure 2A & 2B** presents the temperature distribution in the range from -2 to 1.6˚C for skin type II group and -2 to +1.2˚C skin type IV group, when accounting for extremes.

The automated application temperature values achieved a smaller range than the manual application values. The skin type II group values plotted in **Figure 3** fit into the temperature range of -0.4 to 0.4˚C, whereas the skin type groups IV and V fall into a larger range of -0.4 to 0.8˚C.

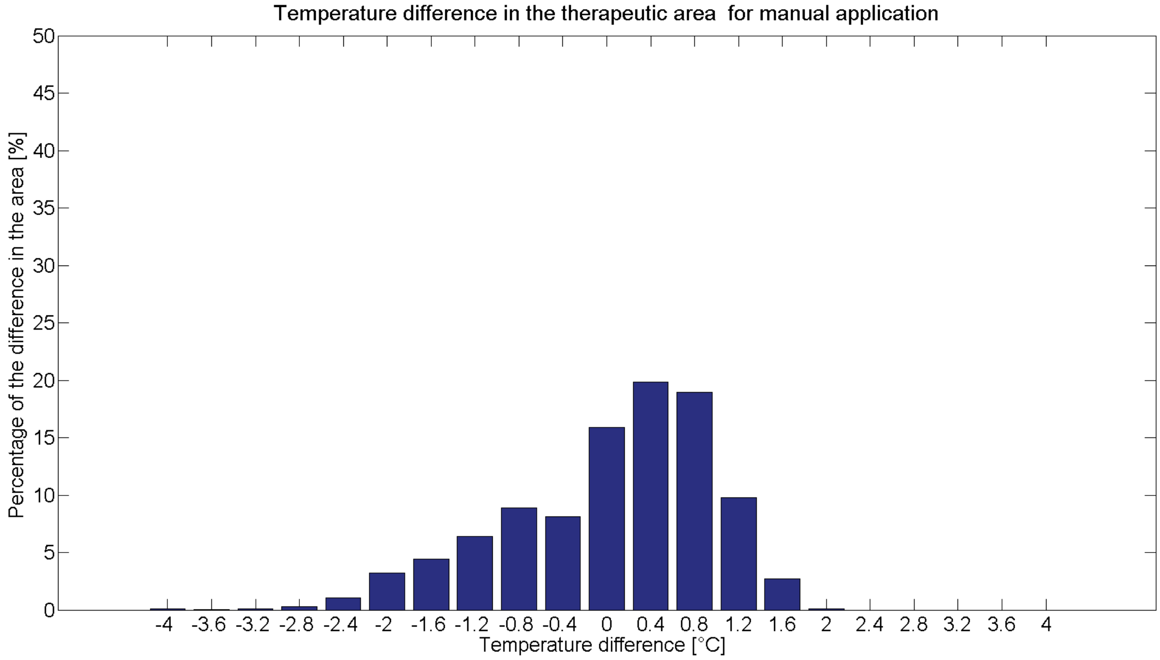

Figure 2A. Normalized histogram of the mean difference values for manual application for skin type II group.

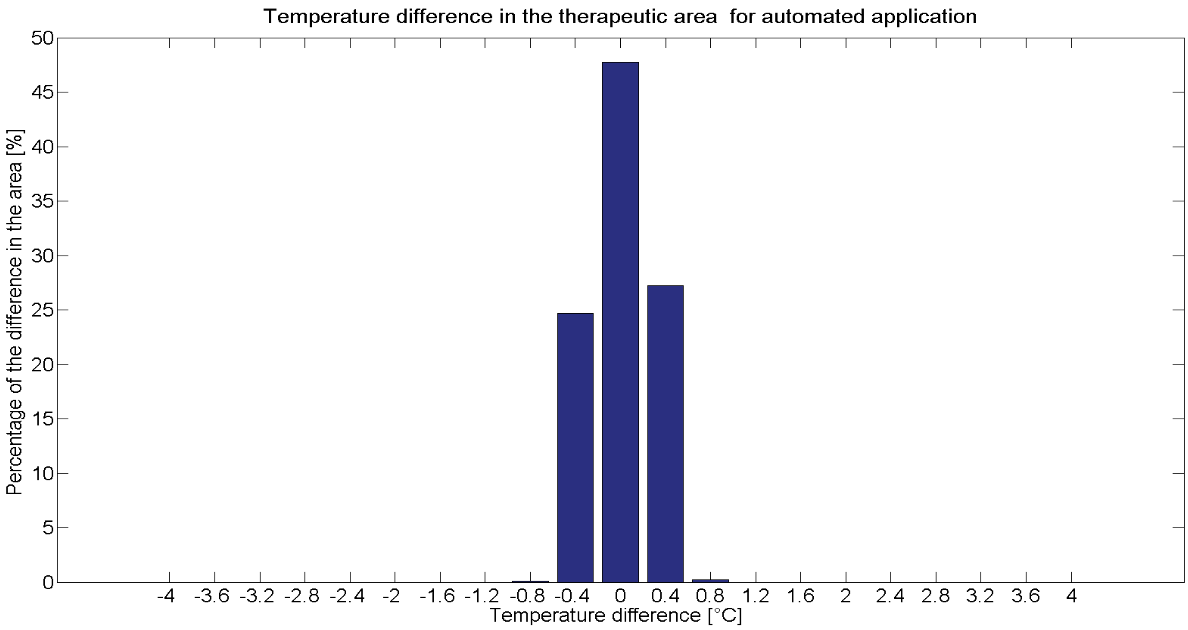

Figure 2B. Normalized histogram of the mean difference values for automated application for skin type II group.

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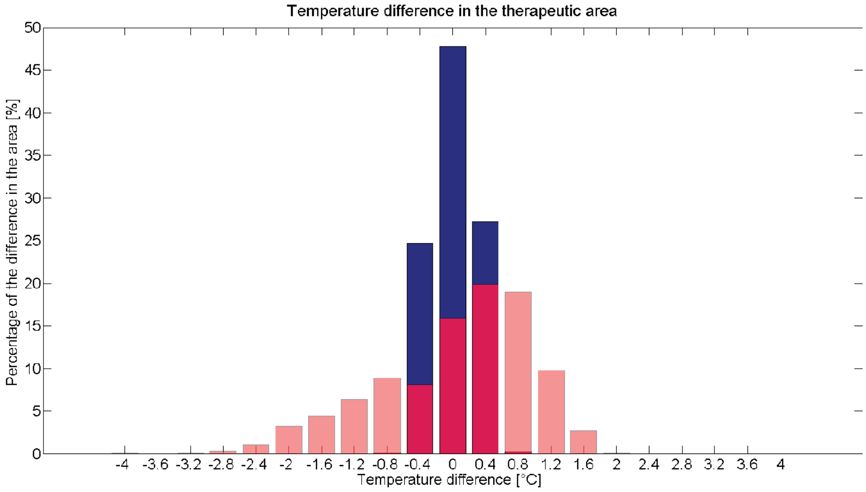

Figure 3. Comparison of the average difference values for automated (in blue colour) and manual (red colour) applications.

Homogeneity Coefficient Evaluation

HC refers to the average percentage of energy for one "temperature difference group". HC were calculated for both the automated and manual applications. A higher HC value results in a lower distribution of temperatures, in turn increasing the homogeneity of the application.

For the automated application the average value of the homogeneity coefficient were 40.66 ± 10.04 for the skin type II group and 39.31 ± 5.33 for skin type IV group. Average value for manual therapy was 18.77 ± 3.99 for the skin type II group and 20.17 ± 3.74 for the skin type IV group **(Table 1).**

Table 1. Average homogeneity coefficient for the applications.

Homogeneity coefficient	
Scanning system: Skin type II	0.4066 ± 0.1004
Scanning system: Skin type IV	0.3931 ± 0.0533
Manual therapy: Skin type II	0.1877 ± 0.0399
Manual therapy: Skin type IV	0.2017 ± 0.0374

A significant ($p>0.01$) difference was observed between the manual application and automated application for both skin type groups based on the Mann-Whitney U-test.

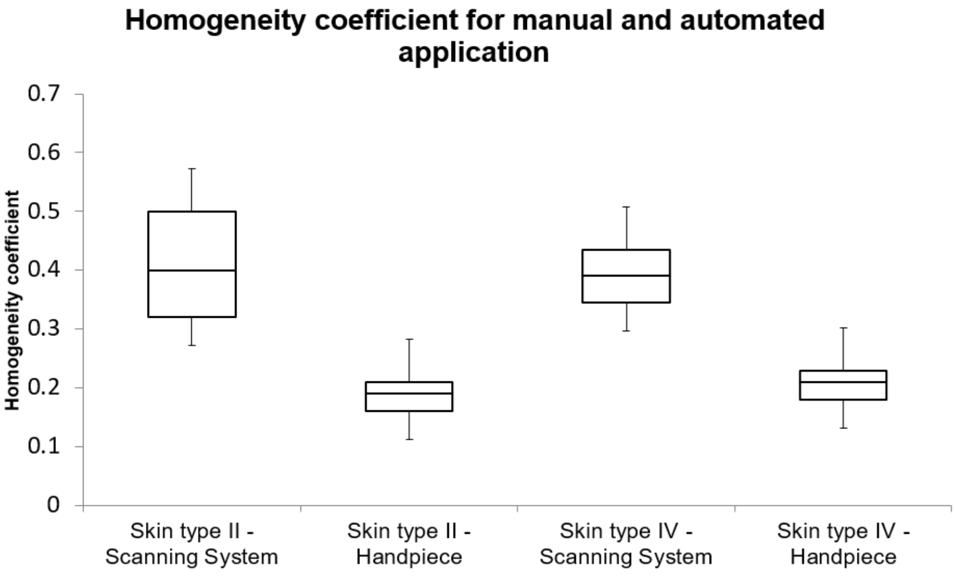

Figure 4. Homogeneity coefficient for manual and automated applications.

Additionally, there was no significant difference ($p>0.01$) for either application on different skin type groups.

DISCUSSION

Laser therapy is a popular physical modality for the pain relief and bio-stimulation which can be delivered by conventional manual application. Currently, the development of automated solutions for laser application is in demand in order to save operators time and reduces strain, mainly for application on large areas. No side effects or patient burns were reported.

The aim of the experiment was to evaluate the homogeneity of the spread of the energy delivered by a manual hand piece and automated scanning applicator using a 30 W maximum power output and a single 1064 nm wavelength on the area of 100 cm^2, something that has never been measured before for high intensity (Class IV) lasers with such given parameters. By doing so, one could better understand how energy is distributed on patient's skin of various skin types (According to the Fitzpatrick Scale). It should be worth noting that no therapeutic evaluation was in the scope of this study, rather it focused on understanding energy distribution on patients skin. Moreover, no side effects or burns were reported by patients who received the therapy.

To better make these evaluations, we must understand the operation of laser therapy devices. Laser therapy devices use a therapeutic spot which can vary within centimeters in diameter. Higher penetration can be achieved by using a spot with a diameter around 10 mm [3], hence our justification for using this spot diameter in our study. Notwithstanding, it is difficult to achieve a homogenous energy spread by controlling a laser applicator manually due to human error where it is impossible to reproduce each and every hand movement in exactly the same pattern. Controversially, an automated application could allow for precise control of the spot and increase the homogeneity of the energy spread. Based on the results from our three evaluation criteria, we can conclude that automated therapies provided a more homogenous spread of energy on relatively large areas.

We visually evaluated and monitored the number of colored heat signatures of the therapeutic area from the thermal image which displayed a greater homogenous spread for the automated application, mainly for the edges of the therapeutic area (which matched our pre-treatment outline markings). Due to the subjectivity of this evaluation method, we further supported our findings by assessing the temperature difference in the therapeutic area, as well as evaluated the HC for each skin type and application.

Mean temperature value and individual differences were calculated for the 10x10 cm therapeutic areas to have one normalized parameter, the homogeneity coefficient. Results in **Figure 4** show the trend of accumulation of energy within two degree difference for the automated application for skin type II. In comparison, the less homogenous manual application had differing temperature values within 4 degrees. This was confirmed by the visual evaluation of the images **(Figure 1).**

The HC was calculated based on the number of differential points (0.4˚C) and average distribution in the therapeutic area. Inclusion limit was more than 3% to exclude the extremes in the image. This evaluation parameter combines the width and height of the distribution graph and carries the complex information about the temperature spread on the patient. A higher HC value results in a lower distribution of temperatures, in turn increasing the homogeneity of the application. A higher average homogeneity coefficient was calculated for the automatic application (39.31 ± 5.33) for both groups of skin type compared to the manual application. No significant difference was observed between the groups. This is of particular importance as this result provides consistency in our results with both skin types tested and confirms the homogeneity energy spread delivered by the automatic and manual application was independent to the skin type.

CONCLUSION

From our results, we can conclude that Class IV laser therapy with a single 1064 nm wavelength and 30 W power using the automated scanning system application on an area of 100 cm^2 provided a more homogenous energy spread, resulting in a more effective therapy than the manual hand piece application. Moreover, due to the accurate small spot size we were better able to penetrate into deep structures with maximal control while providing a safe, time effective and less demanding environment for both the patient and operator.

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