

## EFFECT OF LOW-LEVEL LASER THERAPY ON DIABETIC FOOT ULCERS

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### Abstract

**Background:** Across the globe, diabetes mellitus (DM) is considered as a major health issue because of its prevalence rate tending to increase day by day in a remarkable manner. A foot ulcer is frequently faced complication that is very frequently faced in patients suffering from diabetes mellitus. Diabetic Mellitus is noticed as a severe health issue affecting around 387 million people. The purpose of this study is to study the effect of low level laser therapy on diabetic foot ulcers to control infection, determine best suitable cost-effective technique and aid in studying the role of Low-level laser therapy in the context of treating diabetic foot ulcers.

**Aim:** To study the role of low-level laser therapy on diabetic ulcers

**Results:** The proportion of males was slightly higher than females in both cases and controls. The mean BMI was  $26.50 \pm 2.444$  among cases and mean BMI was  $25.27 \pm 2.407$  among controls. Among 16 grades 1 ulcer, 6 (37.5%) remained in grade 1, 10 (62.5%) ulcers completely healed at the end of 20 days. In group B, 21 subjects had bacterial growth on day-1, and the remaining 19 had no bacterial growth. Out of the 21 with bacterial growth, 15(71.42%) still had growth at the end of 20 days, and 6 (28.58%) had no growth.

**Methods:** The current study was a randomized open labelled control study, with randomised two treatment groups [Group A: Intervention group (who received laser therapy in addition to standard management) Group B: Control group (standard treatment group)] and total sample size of 80 performed at the Department of Surgery, Banas Medical College and Research Institute, Palanpur, Gujarat between Jan-17 to Dec-17.

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like a bar diagram, pie diagram and box plots. The area of the ulcer was compared between the two groups, using independent sample t-test. The mean differences along with their 95% CI were presented. Association between quantitative explanatory and outcome variables was assessed by calculating the Pearson correlation coefficient and the data was represented with P-value.

**Conclusion:** It can be concluded that Laser therapy is best-suited therapy for curing the diabetic foot ulcer as it is pain-free, effective on budget, wound contraction as well as re-epithelialisation helped in accelerating the curing of the wound with simple curing process following proper medication and instructions provided with laser therapy. Control of infection becomes easy as compared to any other techniques being used such as split skin grafting, and other secondary expensive procedures attempted to cure DFU.

### Introduction:

Across the globe diabetes mellitus (DM) is considered as a major health issue because of its prevalence rate tending to increase day by day in a remarkable manner<sup>1</sup>. A foot ulcer is frequently faced complication that is very frequently faced in patients suffering from diabetes mellitus<sup>2,3</sup>. Diabetic Mellitus is noticed as a severe health issue affecting around 387 million people. 25% of lifetime risk is involved in case of diabetic patients of getting affected by diabetic foot ulcer that leads to limb amputation on average in one of seven patients suffering from Diabetic foot ulcer<sup>4</sup>. It is termed as a dreaded

disability with long hospital stays, increased expenses in treating the disability being faced and is characterized by a classical triad of neuropathy, infection and ischemia<sup>5</sup>.

Diabetic foot ulcer requires proper care to be taken of the wound or sepsis being experienced. It serves as a major cause for various risk factors associated with DFU (Diabetic foot ulcer) such as morbidity, amputation and gangrene. Physical and Psychological stress may be experienced in patients that affect productivity and lead to financial problems found in patients<sup>6</sup>. Peripheral vascular disease, foot deformities as well as the presence of callus are the

consequences faced with diabetic foot ulcers with an estimated 15% of diabetic individuals in a lifetime. In India, it is estimated that 40,000 legs are noticed to be amputated with 75% if neuropathic infection with factors such as walking, illiteracy and low socioeconomic status with diabetic foot care taken with the help of physicians<sup>7</sup>.

Various risk factors associated with DFU is associated with sensory, motoric and autonomic terms with the peripheral arterial occlusive disease is correlated with limited joint mobility, foot deformation, and improper footwear used. Postul-cerative lesion deals with gangrene of the foot. Different laser wavelength deals with the depth of penetration into human tissue. Therapeutic methods used deals with multiple issues such as wound cleaning, debridement, grafting of the skin, antibiotics being used, vasodilators, management in pain and making use of bandages with the utilisation of fly maggots as well<sup>8</sup>.

Low-level laser therapy is termed as soft laser light direct supply of bio-stimulative energy to body cells can be done to treat foot ulcers. The absorbed laser energy helps in the stimulation of cells with the rapid and significant increase in temperature of tissues. LLLT with laser acupuncture needle inserted in the upright position, with high optical density with fibre scattering occurring in similar dimensions with different laser wavelength depends upon the depth of penetration in human tissues for treating different foot ulcer types<sup>9</sup>.

It is observed in most of the prevailing cases in India deals with low-level laser therapy helps in avoiding the backlog of the implementation processes with diabetic ulcers associated with wound healing is required to control the infection, cost-effectiveness with procedures of skin grafting. In cases of diabetic ulcers use of dressing required to heal the wound, the negative pressure created with hyperbaric oxygen treatment, electrical, electromagnetic with shockwave with different ultrasound therapies used for growth and biological factors can adjust well in treatment options best suitable for various patients<sup>10</sup>.

LLLT is used as a suitable therapy suggested for neovascularization and collagen remodelling. It assists in modulating the expression of inflammatory mediators that lead to a reduction in edema, leukocyte, influx and managing levels of oxidative stress<sup>11</sup>. The purpose of this study is to study the effect of the effect of low-level laser therapy on diabetic foot ulcers to control infection, determine

best suitable cost-effective technique and aid in studying the role of Low-level laser therapy in the context of treating diabetic foot ulcers.

### **Aim**

To study the role of low-level laser therapy on diabetic ulcers (Reduction in size of the ulcer, faster-wound healing, control of infection, cost-effectiveness and if secondary procedures like split skin grafting can be avoided).

### **Materials and Methods**

The current study was a randomized open labelled control study, with randomised two treatment groups [Group A: Intervention group (who received laser therapy in addition to standard management) Group B: Control group (standard treatment group)] and total sample size of 80 performed at the Department of Surgery, Banas Medical College and Research Institute, Palanpur, Gujarat between Jan-17 to Dec-17.

All patients in both the groups received the required, conventional treatments of diabetic wound care, including dressing, antibiotics, controlling diabetes, cholesterol, and blood pressure along with aggressive drug treatment and wound debridement when needed, before, after and during the laser therapy procedure. Patients in the study group received treatment with LLLT. Ulcer bed with edge was irradiated locally with red light (660nm). Ulcer size and its depth were used as a basis to calculate the duration of exposure to deliver 4- 8J/cm<sup>2</sup> for 20 minutes, for 20 days on a daily basis. The conventional dressing was preferred for covering after irradiation and controls were treated with conventional therapy alone, which includes dressings with betadine or wet with saline, course of antibiotic treatment and slough removed whenever needed.

At baseline and day 20, the size of the ulcer was measured with a ruler. Wound swab for culture and sensitivity was taken both in the control and study group on day 0 and day 20. Grade of ulcer assessed before starting the treatment and on day 20. Systemic antibiotics were suggested to use with the help of culture sensitivity reports. Good glycemic control was maintained by having Insulin/oral hypoglycaemic agents (OHA) on the advice of the physician. Informed consent was obtained from each study participant, after explaining the risks and benefits involved in the study and voluntary nature of

participation, in a language participant can understand.

Area of the ulcer was considered as the primary outcome variable. The mode of treatment standard vs Intervention) was considered as the primary explanatory variable. Various demographic, diabetes disease-related, and treatment related parameters were considered as other potential confounding variables. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using

appropriate diagrams like a bar diagram, pie diagram and box plots.

Both the study groups were compared at the baseline with respect to all potential confounders. The area of the ulcer was compared between the two groups, using independent sample t-test. The mean differences along with their 95% CI were presented. Association between quantitative explanatory and outcome variables was assessed by calculating the Pearson correlation coefficient and the data was represented with P-value.

**Results**

**Table 1: Comparison of the mean area across study groups on day 1 and 20 (N=80).**

Parameters	Cases (G1) Mean±STD	Control (G2) Mean±STD	Mean difference	95% CI Lower	Upper	P-value
Day-1 area	12.65±10.88	18.90±14.03	-4.2580	.17.62	0.038	0.041
Day-20 area	3.90±5.21	17.70±18.70	-13.7230	-21.01	-9.628	<0.001
Changes in Area	8.57±6.83	0.35±2.37	8.4856	4.601	12.259	<0.001

Among the study participants, 40 (50.00%) were Cases, and 40 (50.00%) were Controls. The mean Age was 51.0±7.840 in cases and mean Age was 50.55±10.52 in controls. The mean difference across the group is (-0.38), and it is statistically not significant (p-value 0.855). The proportion of male in cases was 24 (60%), and female was 16 (40%) whereas the proportion of male in controls was 26 (65%) and female was 14 (35%). The association of gender with the study groups was statistically not significant (p-value 0.041).

The proportion of males was slightly higher than females in both cases and controls. The mean BMI was 26.50±2.444 among cases and mean BMI was 25.27±2.407 among controls. The mean difference across the group is (0.90), and it is statistically not significant. The mean duration of ulcer in weeks was 4.25±4.665 in controls. The mean difference across the group is (- 5.349). It is statistically significant (p-value 0.051). The mean day 20 area was 3.90±5.21 in cases and 17.70±18.70 in controls. The mean difference across the group is (-13.72). It is statistically significant (p-value < 0.001) the mean changes in area were 8.57±6.83 in cases and 0.35±2.37 in controls. The mean difference across the group is (9.58). It is statistically significant (p-value < 0.001) (Table 1).

**Table 2: The change in the grade of ulcer in group A**

Day 1	Day 20		
	Grade 2	Grade 1	Complete healed
Grade 2 (N=24)	0 (0.00%)	22(91.6%)	2(8.4%)
Grade 1 (N=16)	0(0.00%)	6(37.5%)	10(62.5%)

In study group A, among the 40 subjects, 24 were grade 2 ulcers, and 16 were grade 1 ulcers on day 1. At the end of 20 days, the number of grade 2 ulcers that remained in grade2 was nil. Out of 24 grade 2 ulcers, 22(91.6%) improved to grade1, and 2 ulcers were completely healed at day 20. Among 16 grades 1 ulcer, 6 (37.5%) remained in grade 1, 10 (62.5%) ulcers completely healed at the end of 20 days (Table 2).

**Table 3: The change in the grade of ulcer in group B**

Day 1	Day 20		
	Grade 2	Grade 1	Complete healed
Grade 2 (N=26)	20(76.92%)	6(23.08%)	0
Grade 1 (N=14)	0(0.00%)	14(100%)	0

In study group B, among the 50 subjects, 26 were grade 2 ulcers, and 24 were grade 1 ulcers on day 1. At the end of 15 days, the number of grade2 ulcers that remained in grade 2 was 23 (88.46%) and 3 ulcers (11.53%) improved to grade 1. Among 24 grade1 ulcers, all remained in grade1 and no (0.00%) ulcers healed completely at the end of 20 days (Table 3).

**Table 4: Culture positive status on day 1 and day 20 in group A (N= 40).**

Day 1	Day 20	
	Growth	No Growth
Growth (N= 22)	8 (36.36%)	14 (63.63%)
No growth (N=18)	0	18 (100%)

In group A, 22 subjects had bacterial growth on the day- 1 and the remaining 18 had no bacterial growth. Out of the 22 subjects with bacterial growth, 8 people still had growth at the end of 20 days and 14 had no growth. Among 18 people with no growth, none of them developed new growth on day 20 (Table 4).

**Table 5: Culture positive status on day 1 and day 20 in group B (N= 40).**

Day 1	Day 20	
	Growth	No Growth
Growth (N=21)	15(71.42%)	6(28.58%)
No growth (N=19)	4(21.05%)	15 (78.95%)

In group B, 21 subjects had bacterial growth on day-1, and the remaining 19 had no bacterial growth. Out of the 21 with bacterial growth, 15(71.42%) still had growth at the end of 20 days, and 6 (28.58%) had no growth. Among 19 people who had no growth, 4 (21.05%) cases developed new bacterial growth (Table 5).

**Discussion**

In a study conducted by Home (2008), it was mentioned that the diabetic foot syndrome is one of the most prevalent causes of nontraumatic limb amputations. Diabetic foot problems have a significant financial impact on the national health system and on patients' quality of life when contrasted with the present study it coincides with the views of Home (2008)<sup>12</sup> with the observation that, the incidence of DFU is seen to be increasing in patients of Diabetes mellitus with common complications faces with regards to foot ulcers such as amputation, physical and psychological stress experienced and other problems associated with the quality of life<sup>2</sup>.

**Bacterial Growth and LLLT observation**

LLLT, as a noninvasive, pain-free method with minor side effects, has been considered as a possible treatment option for diabetic foot syndrome. There is not yet a unique explanation of the mode of functioning of laser therapy in the treatment of diabetic ulcers<sup>13</sup>. Biometrical and histological analysis indicated “faster lesion contraction showing quicker

reepithelization and reformed connective tissue with more organized collagen fibers” in irradiated wounds<sup>14</sup>. In the present study, it was observed that the major point of concentration in analyzing the symptoms triggered at bacterial growth and no growth of bacterial by studying its culture is positive or not and the incidence of it among 80 patients subdivided into two groups they are growth and no growth. In group B, 21 subjects had bacterial growth on day-1, and the remaining 19 had no bacterial growth. Out of the 21 with bacterial growth, 15(71.42%) still had growth at the end of 20 days, and 6 (28.58%) had no growth. Among 19 people who had no growth, 4 (21.05%) cases developed new bacterial growth.

**User Grade**

In a study by Priyadarshini et al. (2018)<sup>15</sup> group A, among the 50 subjects 29 were grade 2 ulcers, and 21 were grade 1 ulcers on day 1. At the end of 15 days, the number of grade 2 ulcers that remained in grade2 was nil. Out of 29 grade 2 ulcers 28 (96.6%) improved to grade1, and 1 ulcer was completely healed at day 15. Among 21 grades 1 ulcer, 7 (33.33%) remained in grade 1, 14 (66.67%) ulcers completely healed at the end of 15 days In the present study group A, among the 40 subjects 24 were grade 2 ulcers, and 16 were grade 1 ulcers on day 1. At the end of 20 days, number of grade 2 ulcers that remained in grade2 was nil. Out of 24 grade 2 ulcers, 22(91.6%) improved to grade1 and 2 ulcers were completely healed at day 20. Among16 grades 1 ulcer, 6 (37.5%) remained in grade 1, 10 (62.5%) ulcers completely healed at the end of 20 days.

**Observation and summary**

In a nutshell, it can be said that other clinical studies give enough evidence to continue research on LLLT for diabetic ulcers, but clinical trials using human models do not provide sufficient evidence to establish the usefulness of laser therapy as a standard tool in wound care regimes at this state. Further, well-designed research trials are required to determine the true value of laser therapy in routine wound care<sup>16</sup>. Also, other relevant studies conducted by Whiting (2011) and Cavanagh et al. (2005) were in support of Whinfield (2009). When contrasted with the present study, it was found that Laser therapy is the painless technique, which is a cost-effective procedure as well. It makes use of induces of faster granulation, contraction of wounds and re-epithelialization procedure, hence accelerating the

complete prevention and cure of wound assisting well in avoidance of secondary procedures which are highly expensive at pocket such as split skin grafting. Control of infection was found to be better when compared to control group nature studied in the present study with respect to ulcer grade, bacterial growth status and ulcer size detection and cure measures used to cure it as well.

### Conclusion

It can be concluded that Laser therapy is best-suited therapy for curing the diabetic foot ulcer as it is pain-free, effective on budget, wound contraction as well as re-epithelialisation helped in accelerating the curing of the wound with simple curing process following proper medication and instructions provided with laser therapy. Control of infection becomes easy as compared to any other techniques being used such as split skin grafting, and other secondary expensive procedures attempted to cure DFU. Also, investigation mechanism of LLLT is a significant term to understand and study the effect of it in case of diabetic ulcers such as studying the bacterial growth, ulcer size and other physical and psychological features associated with the patient. Varied patients are treated with various wavelengths being used in combination, and the duration of radiation also varies in frequency. Hence it is evident that LLLT as a treatment method used for treating diabetic ulcer shows a positive outcome and encourages the findings for related investigation as well.

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