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Effect Of INFRAD Device Application On Wound Healing Among Patients With Type II Diabetes Mellitus And Foot Ulcer

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ABSTRACT

Background: Diabetes is the non – communicable chronic health issue. Long uncontrolled diabetes leads to many systematic complications; diabetic ulcer foot is one among them that result in loss of foot or amputation. The aim of the study was to evaluate the effectiveness of INFRAD device on wound healing among Patient with Type II diabetes mellitus and foot ulcer at selected hospital, Puducherry, with the objectives of to evaluate the effectiveness of INFRAD device on wound healing among patients with type II diabetes mellitus and foot ulcer.

Methodology: A Quantitative Research approach of Randomized controlled trail was adopted for this study. The sample size was (30 in experimental group and 30 in control group) which was selected by adopting simple random sampling technique. Pre-test was done to assess the wound healing in experimental and control group with the help of structured questionnaire. Patients in the experimental group received INFRAD device whereas the patient in control group received only the routine hospital care. Post-test was done on the 7th day using the same tool.

Result: The study result revealed that, pre – test mean difference were 0.17 and post-test mean difference were 20.54 respectively and the pre test Independent t value is t = 0.875 and the Post test Independent t value is t = 5.632. There was a statistically significant improvement in the promotion of wound healing in diabetic foot ulcer patient at P<0.001. **Conclusion:** The study concluded that INFRAD Device was very effective in improving wound healing among patient with type II diabetes mellitus and foot ulcer in experimental group when compare to the control group. **Keywords:** Diabetic foot, INFRAD device, wound healing, Diabetes mellitus.

BACKGROUND OF THE STUDY

Diabetes Mellitus (DM) is a chronic metabolic disorder marked by elevated blood sugar due to impaired insulin secretion, action, or both. Type II Diabetes Mellitus (T2DM) is the most common type, characterized by insulin resistance and relative insulin deficiency. It develops gradually due to genetic and lifestyle factors like obesity, inactivity, and unhealthy eating¹. Left untreated, T2DM can lead to serious systemic complications, underscoring the need for early diagnosis and effective management.

Diabetic wounds, especially foot ulcers, are common complications of T2DM caused by neuropathy, poor circulation, and reduced immune defenses. Neuropathy impairs sensation, delaying injury detection, while ischemia slows healing. Untreated ulcers risk severe infection, gangrene, or amputation². Proper wound care, early intervention, and advanced treatments are crucial for improving outcomes and reducing disability.

Wound healing in diabetes is slower due to hyperglycemia-induced issues like impaired immune function, delayed collagen formation, and prolonged inflammation. Oxidative stress and reduced angiogenesis further hinder recovery, making wounds chronic and infection-prone³. Effective management includes controlling blood sugar, improving blood flow, and using therapies that enhance tissue repair.

Several factors slow diabetic wound healing, including hyperglycemia, infections, neuropathy, and poor blood supply. Hyperglycemia weakens immunity and collagen production, while infections prolong inflammation⁴. Neuropathy and vascular issues reduce oxygen and nutrient delivery, further complicating healing. Addressing these factors is key to optimizing wound outcomes.

Complications like neuropathy, peripheral artery disease, and chronic infections make diabetic wounds more challenging to heal⁵. Systemic issues like cardiovascular disease and kidney problems also impact

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recovery. Left untreated, foot ulcers can lead to osteomyelitis, sepsis, or amputation, highlighting the importance of comprehensive wound care in diabetic patients⁶.

NEED FOR THE STUDY

A serious clinical issue, particularly for those with diabetes, are diabetic foot ulcers. They significantly lower the quality of life for patients and can result in major problems, such as amputations. The prevalence of diabetes tends to rise as the world's population ages. Type 2 diabetes is more likely to affect people who are older⁷. The spread of diabetes around the world has been facilitated by the globalisation of unhealth diets and lifestyle choices. If not appropriately monitored and treated, diabetic foot ulcers are a significant consequence of diabetes that can result in other issues⁸. The following are some possible side effects of diabetic foot ulcers: cellulitis, abscess formation, osteomyelitis, gangrene, deep tissue infections, delayed wound healing, amputation, systemic infection and chronic pain⁹. In the treatment of patients with diabetic foot ulcers, nurses are indispensable. They are responsible for numerous facets of assessment, treatment, education, and support¹⁰. The following are some of the main duties that nurses have when treating diabetic foot ulcers: assessment and monitoring, wound care, infection control, pain management, patient education, nutritional assessment¹¹.

Diabetes Mellitus is known to damage multiple organs, including the heart, kidney, eye, and nerves, leading to complications such as heart attack, stroke, blindness, kidney failure, and lower limb amputation. Diabetic foot ulcer (DFU) is a frequent complication that occurs in approximately 6.3% of patients with DM globally¹².

In 2021, approximately 537 million adults (20-79years) are living with diabetes. The total number of people living with diabetes is projected to rise to 643 million by 2030 and 783 million ¹³.

About 422 million people worldwide have diabetes, the majority living in low and middle-income countries, and 1.5 million deaths are directly attributed to diabetes each year. Both the number of cases and the prevalence of diabetes have been steadily increasing over the past decades¹⁴. The annual incidence of diabetic foot ulcer worldwide is between 9.1 to 26.1 million.

In India it is often referred to as the "Diabetes Capital of the World", as it accounts for 17% percent of the total number of diabetes patients in the world¹⁵. India is one of the leading countries, with more than 77 million individuals with diabetes, and that number is estimated to rise to 35.7 million by 2045. Diabetes is prevalent in 8.9% of the Indian population, with an estimated 1 million diabetes-related deaths each year and estimated that nearly 25% of individuals with diabetes patients in India will develop Diabetic foot ulcer¹⁶.

High prevalence of diabetes is reported in economically and epidemiologically advanced states such as Tamil Nadu and Kerala, where many research institutes which conduct prevalence studies are also present¹⁷.

The study shows that the prevalence of diabetes in Tamil Nadu is about 18.1%. Wherever the urban area accounts of 11.2% and rural area accounts of 5.2% in Tamil Nadu.

The prevalence of diabetes in urban area of Pondicherry was 51(8.27%), out of these cases 39(76%)¹⁸.

The Infra-red radiation is one among the best therapy in the healing of diabetic foot ulcer to improve the efficacy¹⁹. The researcher found that Infra-red radiation therapy effective to reduce the complications associated with diabetic foot ulcer such as abscess formation, sepsis, gangrene, foot amputation and foot deformities²⁰. In Infra-red radiation therapy, it improves the tissue granulation, formation and diminishes wound exudation and inflammation²¹.

STATETEMENT OF THE PROBLEM

EFFECT OF APPLICATION OF INFRAD DEVICE ON WOUND HEALING AMONG PATIENTS WITH TYPE II DIABETES MELLITUS AND FOOT ULCER AT SELECTED HOSPITAL PUDUCHERRY

OBJECTIVES:

To evaluate the effectiveness of INFRAD device on wound healing among patients with type II diabetes mellitus and foot ulcer.

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METHODS AND MATERIALS

- A Quantitative research approach of Randomized Controlled trail was conducted to this study. The study was conducted in the male and female surgical wards of Mahatma Gandhi Medical College and Research Institute, Puducherry. Sixty patients with Type II DM and DFUs were included, with equal allocation to experimental and control groups²². The investigator included the participants for this study were Patients of both sex diagnosed with Type II Diabetes mellitus and Foot Ulcer within the grade 0-5 and 40 to 70 years of age and Patients, who are able to understand both Tamil and English and the investigator excluded the participants like Patients with Type I DM or co-morbid conditions such as Alzheimer's or Parkinson's disease²³. The tools used for data collection are Demographic and clinical data were collected using structured questionnaire and Wound healing was assessed using the Bates-Jensen Wound Assessment Tool.
- The investigator give the intervention by using the INFRAD DEVICE, it's a lamb that can be applied over diabetic foot ulcers has been shown to accelerate ulcer healing, improve granulation tissue formation and diminish wound exudation and inflammation. INFRAD therapy helps prevent diabetic foot ulcers is by improving blood flow to the feet. It can also help to reduce inflammation in the feet, which is another risk factor for diabetic foot ulcers. It is the most efficient therapy compared to the other therapy given to the diabetic foot ulcer. The diabetic foot ulcer has been reduced to the some extent by application of INFRAD therapy. It is applied for the period of 15 minutes of duration for the patient. It enhances the wound healing faster compared to the other treatment methods. In the experimental and control group Pre test was done to the diabetic patients who were admitted in the MGMCRI, the samples were selected by using simple random sampling technique. The data were collected from the subjects by using structured tool with interview method. After the pre-test subjects in the experimental group received INFRAD device therapy on wound healing, twice a day with a duration of 10 minutes. Subjects in the control group were not given any interventions other than routine hospital care, routine care include daily dressings, wound and foot care, and medications. Post-test was carried out after 7 days with the same tool which was used for pre-test.

DATA ANALYSIS:

Table 1: Frequency and percentage distribution of demographic variables of the patients with Type II Diabetes Mellitus and Foot Ulcer.

N = 60

Demographic Variables	Experi Group	Control Group (30)		Chi-Square for		
	F	%	F	%	homogeneity	
Age in years					2	
Below 40	7	23.3	9	30.0	$\chi^2 = 0.689$	
40 - 55	13	43.4	10	33.3	d.f=2 p=0.709	
56 - 70	10	33.3	11	36.7	N.S	
Above 70		-	-	-	11.0	
Sex					$\chi^2 = 0.278$	
Male	17	56.7	19	63.3	d.f=1 p=0.598 N.S	
Female	13	43.3	11	36.7		
Residential area					$\chi^2 = 0.734$	
Rural	18	60.0	16	53.3	d.f=2 p=0.693	
Semi urban	8	26.7	11	36.7		
Urban	4	13.3	3	10.0	N.S	
Religion					$\chi^2 = 0.302$	
Hindu	19	63.3	21	70.0	d.f=2	

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Demographic Variables	Experimental Group (30)		Control Group (30)		Chi-Square for		
	F	%	F	%	homogeneity		
Muslim	5	16.7	4	13.3	p=0.860		
Christian	6	20.0	5	16.7	N.S		
Educational Qualification							
No formal education	-	-	-	-	$\chi^2 = 0.607$		
Primary school level	5	16.7	3	10.0	d.f=3		
Secondary school level	16	53.3	17	56.7	p=0.895		
Higher secondary level	6	20.0	7	23.3	N.S		
Collegiate level and above	3	10.0	3	10.0			
Family history of diabetes mellitus					$\chi^2 = 0.480$		
Yes	6	20.0	4	13.3	d.f=1		
No	24	80.0	26	86.7	p=0.488 N.S		
If yes, specify the duration					2		
<1 years	4	13.3	5	16.7	$\chi^2 = 0.316$		
1 – 5 years	14	46.7	13	43.3	d.f=3 p=0.957 N.S		
6 – 10 years	7	23.3	6	20.0			
Above 10 years	5	16.7	6	20.0			
Dietary practices							
High caloric diet	7	23.3	7	23.4	$\chi^2 = 0.814$		
High fiber diet	8	26.7	10	33.3	d.f=3		
More spicy diet	2	6.7	3	10.0	p=0.846		
Restricted diet	13	43.3	10	33.3	N.S		
Others							
Healthy habits					2 2 5 4 2		
Yoga	7	23.3	6	20.0	$\chi^2 = 0.519$ d.f=3		
Walking	15	50.0	16	53.3	p=0.915		
Others	7	23.3	6	20.0	D=0.913 N.S		
All that applies	1	3.3	2	6.7			
Unhealthy habits	2						
Smoking / tobacco chewing	10	33.3	11	36.7	$\chi^2 = 0.373$		
Alcoholism	8	26.7	6	20.0	d.f=2 p=0.830		
Drug abuse	12	40.0	13	43.3	N.S		
None of the above	-	-	-	-			

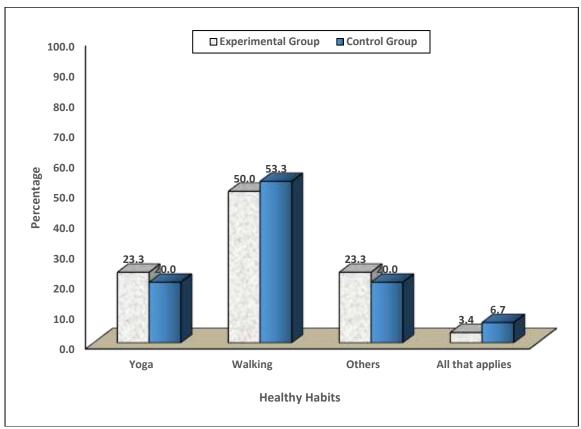
N.S - Not Significant, p>0.05

The table 1 indicates that most of the patients with Type II diabetes mellitus and foot ulcer, 13(43.4%) in the experimental group were aged between 40 – 55 years & 11(36/7%) in the control group were aged between 56 – 70 years, 17(56.7%) in the experimental group and 19(63.3%) in the control group were male, 18(60%) in the experimental group and 16(53.3%) in the control group were residing in rural area, 19(63.3%) in the experimental group and 21(70%) in the control group were Hindus, 16(53.3%) in the experimental group and 17(56.7%) in the control group had secondary school level education, 24(80%) in the experimental group and 26(86.7%) in the control group had no family history of diabetes mellitus, 14(46.7%) in the experimental group and 13(43.3%) in the control group had family history of diabetes

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mellitus for 1-5 years, 13(43.3%) in the experimental group and 19(33.3%) in the control group had taken restricted diet and high fiber diet, 15(50%) in the experimental group and 16(53.3%) in the control group had healthy habit of walking and 12(40%) in the experimental group and 13(43.3%) in the control group had no unhealthy habits.



Percentage distribution of healthy habits among patients with Type II diabetes mellitus and foot ulcer in the experimental and control group

Table 2: Frequency and percentage distribution of clinical variables of the patients with Type II Diabetes Mellitus and Foot Ulcer.

N = 60

Clinical Variables	Experimental Group (30)			rol p (30)	Chi-Square for		
	F	%	F	%	homogeneity		
Fasting blood sugar (mg/dl)					$\chi^2 = 1.122$		
≤99	6	20.0	4	13.3	d.f=2		
100 to 125	14	46.7	18	60.0	p=0.571		
≥126	10	33.3	8	26.7	N.S		
Post Prandial blood glucose level (mg/dl)							
<140	5	16.6	6	20.0	$\chi^2 = 0.375$		
140 - 160	14	46.7	15	50.0	d.f=3 p=0.945		
161 - 180	9	30.0	7	23.3	D-0.943 N.S		
181 – 200	2	6.7	2	6.7			
HbA1c					$\chi^2 = 0.327$		
4 - 6% (Normal)	10	33.3	12	40.0	d.f=2		

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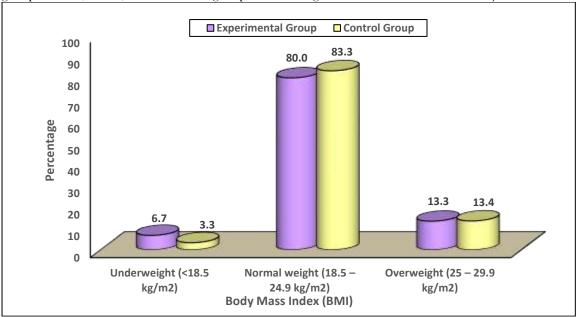
N.S - Not Significant, p>0.05

The table 2 denotes that most of the patients with Type II Diabetes Mellitus and Foot ulcer, 14(46.7%) in the experimental group and 18(60%) in the control group had fasting blood sugar in the range of 100

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to 125 mg/dl, 14(46.7%) in the experimental group and 15(50%) in the control group had post prandial blood glucose in the range of 140 – 160 mg/dl, 15(50%) in the experimental group and 14(46.7%) in the control group had the well-controlled HbA1c in the range of between 6.1 – 7%, 12(40%) in the experimental group had blood pressure in the range of 121 – 130/81 – 90 mmHg & 15(50%) in the control group had blood pressure in the range of 131 – 140/91 – 100 mmHg, 26(86.7%) in the experimental group and 28(93.3%) in the control group had body temperature in the range of 36.1 – 37° C, 24(80%) in the experimental group and 25(83.3%) in the control group had normal BMI, 16(53.3%) in the experimental group and 14(46.7%) in the control group had LDL in the range of 130 – 150 mg/dl, 15(50%) in the experimental group and 18(60%) in the control group had HDL in the range of 130 – 130 mg/dl, 130



Percentage distribution of BMI among patients with Type II diabetes mellitus and foot ulcer in the experimental and control group

Table 3: Effect of application of Infrad Device on Wound Healing among patients with Type II diabetes mellitus and foot ulcer in the experimental group and comparison in the control group. N = 60

Cassa	Pretest			Post Test			Mean Difference	Paired 't' test
Group	Median	Mean	S.D	Median	Mean	S.D	score	& p-value
Experimental Group (30)	42.0	42.47	12.93	21.5	21.93	10.15	20.54	t = 20.683 p=0.001, S***
Control Group (30)	34.0	39.47	13.63	33.5	39.30	13.49	0.17	t = 1.409 p=0.169, N.S

^{***}p<0.001, S - Significant

N.S - Not Significant, p>0.05

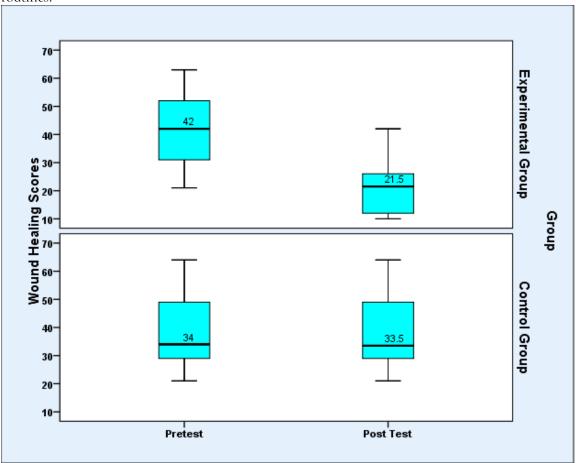
The table 3 shows that in the experimental group, the pretest mean score of wound healing was 42.47±12.93 and the post test mean score was 21.93±10.15. The mean difference score was 20.54. The computed paired "t" test value of 20.583 was statistically highly significant at p<0.001 level which clearly confirms that after the application of Infrad device on wound healing in the experimental group was

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found to be effective in reducing the level of risk among patients with Type II diabetes mellitus and foot ulcer.

The table 3 denotes that in the control group, the pretest mean score of wound healing was 39.47±13.63 and the post test mean score was 39.30±13.49. The mean difference score was 0.17. The computed paired "t" test value of 1.409 was not statistically significant at p<0.05 level which clearly infers that there was no significant difference between the pretest and post test score of wound healing among the patients with Type II diabetes mellitus and foot ulcer in the control group who had undergone normal daily routines.



Boxplot showing the effect of application of Infrad Device on Wound Healing among patients with Type II diabetes mellitus and foot ulcer in the experimental group and comparison in the control group

Table 4: Comparison pretest and post test Wound Healing score among patients with Type II diabetes mellitus and foot ulcer between the experimental group and comparison in the control group. N = 60

Wound Healing	Experimental Group (30)		Control Group (30)		Mean Difference	Student Independent 't' test	
Wound Houning	Mean	S.D	Mean	s.D	score	& p-value	
Pretest	42.47	12.93	39.47	13.63	3.0	t = 0.875 p=0.385, N.S	
Post Test	21.93	10.15	39.30	13.49	17.37	t = 5.632 p=0.001, S***	

^{***}p<0.001, S - Significant

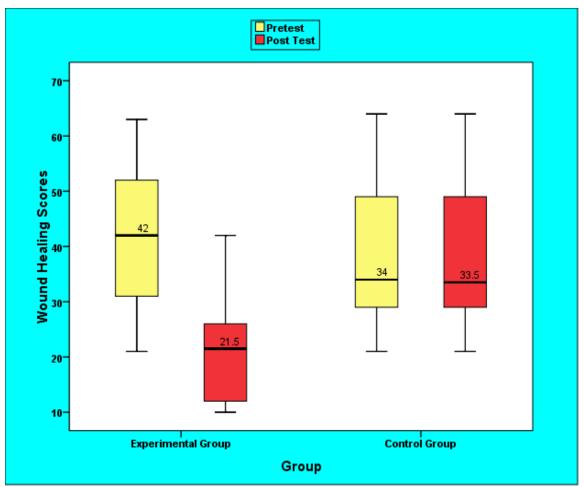
N.S - Not Significant, p>0.05

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The table 4 illustrates that in the pretest, the mean score of wound healing in the experimental group was 42.47±12.93 and the mean score in the control group was 39.47±13.63. The mean difference score was 3.0. The computed student independent t" test value of 0.875 was not statistically significant at p<0.05 level which clearly confirms that there was no significant difference in the pretest score of wound healing between the two groups.

The table 4 indicates that in the post test, the mean score of wound healing in the experimental group was 21.93±10.15 and the mean score in the control group was 39.30±13.49. The mean difference score was 17.37. The computed student independent "t" test value of 5.632 was statistically significant at p<0.001 level which clearly infers that there was significant difference between the post test score of wound healing among the patients with Type II diabetes mellitus and foot ulcer between the two group in which the patients in the experimental group had significant reduction in the risk score than the patients in the control group.



Boxplot showing the comparison pretest and post test Wound Healing score among patients with Type II diabetes mellitus and foot ulcer between the experimental group the control group.

DISCUSSION:

The First objective of the study is to evaluate the effectiveness of INFRAD device on wound healing among patients with type II diabetes mellitus with foot ulcer.

The present study revealed that wound healing process was improved among patients with diabetic foot ulcer. The paired "t value on comparison of wound healing among patients with type 2 Diabetus Mellitus in experimental group between pre and post test revealed the statistical significance difference at p-value < 0.001 with t value 20.683. It denotes that INFRAD device is effective to promote wound healing among experimental group participants. The comparison of pre and Post test score on wound Healing in control

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group participants revelaed no stastistical significally difference with t value 1.409, It shows that routine care is not effective to promote the wound healing among patients with Type 2 Dibetes Mellitus. The independent t value on comparison of pre test score on wound healing between experimental and control group revealed no stastically significally difference with t value 0.875.

The comparison of Post wound healing score between experimental and control group revealed stastically difference at p-value < 0.001 and t value 5.632. It is evident from these findings that INFRAD device is very effective to promote the wound healing among patients with Type 2 Diabetus Mellitus in experimental group than control group participants.

It is substianed by the study findings of Chi-Wen Lung et al., (2021) conducted a quasi-experimental study on Effect of Far Infrared Radiation Therapy on Improving Microcirculation of the Diabetic Foot. The subjects were separated into two groups²⁴. One group consisted of 10 diabetic patients with vascular disease symptoms and one group of 4 healthy non-diabetic Effect of Far Infrared Radiation Therapy on Improving Microcirculation 157 patients. Both groups conducted far-infrared product evaluation, did not change the diet and lifestyle adjustments during the trial, and signed the consent form. The participants were assessed for their microvascular function before and after the interventions in each month for three consecutive months. The results showed that surface temperature increase by 2° after using the pad in the first and third months (p < 0.05); and blood flow increase on the plantar foot (p < 0.05) but not on the dorsal foot. The increase in blood flow may alleviate diabetic-related complications. We tested the use of electric heating pads to improve diabetic foot blood circulation, experimental results show that heating pads can promote lower limb blood circulation in diabetic patients. At the same time, they will affect the autonomic nervous system, but may be affected by terminal neuropathy²⁵. The study concluded that the biological effects of infrared light can improve the blood circulation of the foot at a suitable temperature. Chitra F., et al., (2020) done a quasi-experimental study on Red and Near- Infrared Light-Induced Photobiomodulation Therapy on Wound Healing among Patients with Diabetic Foot Ulcers. 60 patients were selected and assigned randomly to the Experimental and Control group. The patients in the Experimental group received Red and Near-Infrared Light-Induced Photobiomodulation Therapy (Red light-660nm; Near-Infrared-980nm) while the patients in the Control group received conventional therapy for a period of 15 days. Assessment of the wound status was done on day 1 and day 15. The results predicted that the intervention has worked towards reducing the size of ulcer by an average of 4.5cm2 as well as improving the wound status by decreasing the mean total score by an average of 12.250 in the Experimental group. Hence, the intervention was found to be effective in speeding up the wound healing process among patients with DFUs. Based on the results, it's proven that there was a statistically significant difference in the wound status after Red and Near Infrared Light-Induced Photobiomodulation Therapy Hakim A S., et al., (2020) done a clinical trial on Effect of Infrared Radiation on the Healing of Diabetic Foot Ulcer. 50 patients referred to Dr. Ganjavian hospital in Dezful city, Iran, with diabetic foot ulcer degree 1 and 2 (based on Wegener Scale). Sample size was determined based on relevant studies of the recent decade. Patients were classified into the intervention and control groups (n = 25 in each group) in terms of age, gender, degree of ulcer, ulcer site and body mass index. In this study, work progress was evaluated according to the checklist of diabetic foot ulcer healing evaluation. The results of the current study showed that there was a statistically significant difference in healing ulcers (P < 0.05) and mean healing time ($P \le 0.05$) between the two groups. The study concluded that using the infrared plus routine dressing is more effective than using merely routine dressing ²⁸.

Hence the states research hypothesis H1 INFRAD Device has an impact on wound healing among patients with Tpye 2 Diabetteus Mellitus and foot ulcer is accepted.

CONCLUSION

Diabetes mellitus is a chronic multisystem disease related to abnormal insulin protection, impaired insulin utilization, or both²⁶. Diabetes mellitus is a serious health problem throughout the world and its prevalence increasing rapidly. Management of diabetes mellitus requires ongoing interaction among the patient²⁹.

family, and the health care team. It is important that a diabetes nurse educator be involved in the care of

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the patient and the family³⁰. The main aim of the present study was to evaluate the effectiveness of application of INFRAD device on wound healing among patients with type II diabetes mellitus and foot ulcer at selected hospital. The study concludes that the regular practice of INFRAD lamp promotes the wound healing in diabetic foot ulcer.

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