COMPARISON BETWEEN LOW AND HIGH PRESSURE NEGATIVE PRESSURE WOUND THERAPY (NPWT) IN DIABETIC FOOT WOUND IN TERM OF WOUND SIZE REDUCTION AND WOUND BED PREPARATION FOR SECONDARY PROCEDURE

DR NOR HAFIZAH BINTI ZARULLAIL

DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE (ORTHOPAEDIC)

SCHOOL OF MEDICAL SCIENCES

UNIVERSITI SAINS MALAYSIA

2020

ACKNOWLEDGEMENT

First and foremost, I would like to thank Allah S.W.T for giving me the strength, courage, and opportunity to finish this dissertation to fulfil requirement for degree of Master of Medicine (Orthopaedic). As I remember those moments of feeling lost and not having a clue as to what or how to write and complete this thesis, I cannot help but acknowledge divine hand 1 received in so many instances and ways.

My greatest gratitude to the following individuals to their contributions during the preparation and completion of the dissertation

- Professor Dr Amran Ahmed Shokri, who is my supervisor for giving me full support and guidance to complete my dissertation
- All lecturers from Department of Orthopaedic, Universiti Sains Malaysia
- Colleagues and House Officers in Department of Orthopaedic, Universiti Sains Malaysia
- My parents, father Zarullail bin Samsuri, mother Normala binti Ibrahim that gave me motivation, support physically and emotionally to ensure this mission is accomplished.

ABSTRAK

Latar belakang dan objektif: Rawatan ulser kaki pesakit diabetes merupakan masalah yang mencabar kerana kekurangan rintangan badan terhadap jangkitan dan kehadiran penyakit arteri perifer pada pesakit diabetes. Penggunaan terapi luka tekanan negatif (NPWT) untuk memudahkan penyembuhan ulser kaki pesakit diabetes telah dikaji oleh ramai orang. Sehingga kini, tekanan optimum untuk NPWT adalah -125 mmHg. Tujuan kajiaan ini adalah untuk membandingkan keberkesanan tekanan rendah (-50 mmHg) dan tekanan tinggi (-100 mmHg) NPWT dari segi pengurangan saiz luka dan penyediaan luka yang optimum untuk prosedur sekunder.

Reka bentuk dan kaedah kajian: Kajian ini adalah merupakan kajian percubaan terkawal intervensi yang dilakukan secara rawak terhadap pesakit diabetes dengan ulser di kaki yang dimasukkan ke wad ortopedik, Hospital Universiti Sains Malaysia. Sejumlah 58 pesakit dibahagikan secara rawak kepada 2 kumpulan sama ada tekanan rendah (-50 mmHg) atau tekanan tinggi (-100 mmHg) NPWT. Hasil yang diukur adalah pengurangan saiz luka dan skor penyediaan luka. Data demografi pesakit dikumpulkan dan analisis statistik dilakukan dengan meggunakan analisa variasi ukuran (ANOVA) untuk menetukan hubungan antara rawatan dan hasil yang diukur.

Keputusan: Kedua-dua kumpulan rawatan menunjukan perubahan signifikan dari segi pengurangan saiz luka dan skor penyediaan luka. Walau bagaimanapun tidak ada perbezaan yang signifikan apabila membandingkan kedua-dua kumpulan rawatan dengan hasil yang diukur.

Kesimpulan: Terapi luka tekanan negatif membantu penyembuhan ulser kaki pesakit diabetes dengan mengurangkan saiz luka dan mempercepatkan penyediaan luka untuk prosedur sekunder. Dan di dalam kajian ini didapati tidak ada perbezaan yang signifikan antara tahap tekanan negatif yang digunakan**.** Tahap tekanan negatif yang digunakan harus disesuaikan dengan pesakit individu dan tujuan rawatan.

ABSTRACT

Introduction: Healing of diabetic foot ulcer is often a challenging problem due to lack of resistance against infection and presence of peripheral arterial disease in diabetic patients. The use of negative pressure wound therapy (NPWT) to facilitate the healing of diabetic foot ulcer had been studied by many people. To date, the optimal pressure for NPWT was -125mmHg. The aim of this study is to compare the effectiveness of low pressure (-50 mmHg) and high pressure (-100 mmHg) NPWT in term of wound size reduction and optimal wound bed preparation for secondary procedure.

Methodology: This was a prospective interventional, randomized controlled trial study done on patients with diabetic foot ulcer admitted to orthopaedic ward, Hospital Universiti Sains Malaysia. A total of 58 patients which were randomly assigned into 2 groups either low pressure (-50 mmHg) or high pressure (-100 mmHg) NPWT and the outcome measured were wound size reduction and wound bed score. Patients demographic data were collected and statistical analysis was done using repeated measure analysis of variance (ANOVA) to determine the relationship between the treatment and outcomes measured.

Result: Both treatment groups show significance changes in term of wound size reduction and wound bed score. However there is no significance difference when comparing in between both treatment group with measured outcomes.

Discussion/Conclusion: Negative pressure wound therapy facilitate the healing of diabetic foot ulcer by reducing the wound size and expediates wound bed preparation for secondary procedure even though there were no significance difference in between the level of negative pressure used. The level of negative pressure used should be tailored to individual patient and the aim of treatment.

CHAPTER 1 - INTRODUCTION

1.1 INTRODUCTION AND LITERATURE REVIEW

Over the past few decades, diabetes mellitus (DM) has emerged as one of the most prevalent chronic diseases worldwide. In Malaysia, a recent study reported that the overall prevalence of DM among Malaysians was 22.9% in year 2013, and 12.1% of them were newly diagnosed diabetics (1).

Diabetic foot is one of the major concerns in complications of chronic diabetes and is defined as a foot affected by ulceration that is associated with neuropathy and/or peripheral arterial disease of the lower limb in a patient with diabetes (2). Diabetic foot complications resulted in increased hospital bed occupancy and account for increasing healthcare cost and resources (3). Ulceration, infection, gangrene and amputation are significant complications of the disease.

Diabetic foot ulcer (DFU) affects 15% of people with diabetes. The rate of diabetic foot increases year by year. In the National Health and Morbidity Survey 2006 conducted by the Health Ministry, 4-7% of known diabetics had undergone toe or leg amputations.

Diabetic foot ulceration is a major diabetes complication and its management involves a multidisciplinary approach. Proper treatment for diabetic foot ulcer can lower the risk of limb amputations (4).

Reconstruction of diabetic foot ulcers is often a challenging problem. The impairment of the healing process and the lack of resistance against infections in patients with diabetics represent a familiar clinical problem. Surgical debridement of the diabetic foot wounds usually resulted in loss of soft tissue which eventually need for closure using split-thickness skin grafts or transposition flaps. However, immediate surgical closure often fails because the general conditions of patient and wound may not be appropriate for surgical closure; therefore, initial

steps consists of standard wound care (moist gauze dressing) to prepare the wound bed for final closure. This standard wound care will result in prolonged hospital stay thus increasing the hospital cost.

Negative pressure wound therapy (NPWT) was developed by Argenta and Morkywas to promote the healing of open wounds (5). In clinical and experimental studies, effects of the negative pressure are reported as increase of local blood flow, formation of granulation tissue and decrease bacterial colonization. The faster wound healing results in decreased hospitalization and avoidance of additional morbidity in chronic wounds. NPWT is a treatment that has become widely adopted for a broad range of wound indications since its advent over 15 years ago (6) . Supporting evidence for NPWT in the treatment of diabetic foot wounds includes numerous prospective and multi-centered randomized controlled trial (7).

Diabetic foot ulcers were typically chronic wounds which were difficult to heal. This was due to a range of pathogenic abnormalities in diabetics which included ischemia and intrinsic defect of angiogenesis and impaired immunity against infection. Negative pressure wound therapy (NPWT) was developed by Argenta and Morykwas to promote healing of open wounds. In clinical and experimental studies, effects of the negative pressure are improve local blood flow, Induce macrodeformation, induce granulation and angiogenesis, reduce edema and reduce bacterial colonization (7). The negative pressure provides a moist wound bed, which is required for faster healing of chronic open wounds. Faster wound healing during the treatment of diabetic foot ulcers may decrease hospital stay which in turn lower the cost of treatment and additional morbidity of infection and pain. Many studies have been done to prove the effectiveness of negative pressure wound therapy in the treatment of diabetic foot wound.

The negative pressure wound therapy (NPWT) group proportion was significantly (P=0.007) greater for complete ulcer closure than that for advanced moist wound therapy (AMWT) group. In assessing ulcer area, a significant difference between NPWT and AMWT from baseline was

achieved on day 28 (P=0.021). In terms of effect on wound bed preparation, the Kaplan-Meier median estimates for 76-100% granulation tissue formation were 56 days for NPWT and 114 days in AMWT (P=0.022) (8).

The early appearance of granulation tissue in group received negative pressure dressing was found to be statistically significant compared to group received conventional saline moistened gauze dressing. There was a statistically significant ($P< 0.05$) in terms of the mean decrease in wound size in patients with negative pressure dressing compared with conventional saline dressing. This study also observed that patients with negative pressure dressing showed rapid clearance of bacterial load as compared to saline dressing. Although statistically the time status of wound closure was comparable in both groups ($P>0.10$), it was seen that the patients in negative pressure dressing showed faster healing as compared to the conventional saline dressing (9).

Wounds treated with a 125 mmHg vacuum had filled with granulation tissue by day 8. At this time wounds treated with 25 mmHg had filled with 21.2% with new granulation tissue, and wounds treated with 500mmHg had filled 5.9% with new tissue. In conclusions, wound treated with a 125mmHg vacuum exhibited a significant ($p < 0.0001$) increase in the rate of granulation tissue formation compared with treatment at 25 mmHg or 500 mmHg (10).

Wound contraction and fluid removal increased gradually with increasing levels of negative pressure until reaching a steady state. Maximum wound contraction was observed at -75mmHg. When negative-pressure wound therapy was discontinued, after 72 hours of therapy, the wound area was smaller than before therapy. Maximum wound fluid removal was observed at -125 mmHg (11).

Blood flow changed gradually with increasing negative pressure until reaching a study state. At 2.5cm from the wound edge, blood flow increased 6% at -10mmHg, 32% at -45mmHg, and 90% at -80mmHg. Higher levels of negative pressure did not have additional blood flow effect

($p>0.30$). This study implies that -80mmHg has similar blood flow effects as the clinical standard, -125mmHg (12).

1.2 JUSTIFICATION OF STUDY

The conventional NPWT systems adopts either intermittent or continuous mode. In experiments performed on the animal models, it has been shown that the intermittent mode showed increased perfusion level and formation granulation tissue compared to continuous mode. Despite the effectiveness of the intermittent mode in wound healing, it has been avoided in clinical application because of the pain occurring every few minutes during the initiation phase to reach the optimal pressure. Thus the cyclic NPWT was introduced and it shows reduced in patient discomfort while maintaining superior wound healing effects as the intermittent mode (3). The cyclic NPWT system is similar to the intermittent mode in terms of using the same maximal subatmospheric pressure but the pressure never reaches zero in the cyclic mode. So, it continuously creates certain pressure gradient that oscillates between -125mmHg and the preset subatmospheric pressure. Since the introduction of the cyclic NPWT system which its pressure oscillates in between 2 pressure difference, we want to know which pressure is more effective. This study will use -50 mmHg as the low the pressure and -100mmHg as the high pressure as this level is within the recommended therapeutic range. Although the standard pressure for NPWT is -125mmHg, it is not used in this study because it is difficult to set pressure at -125mmHg using the suction wall regulator which will be connected to the vacuum source in ward. The goal of this study is to compare the effectiveness of low and high pressure negative wound therapy in term of wound size reduction and optimal wound bed preparation.

CHAPTER 2 - STUDY PROTOCOL

2.1 DOCUMENT SUBMITTED FOR ETHICAL APPROVAL

COMPARISON BETWEEN LOW AND HIGH PRESSURE NEGATIVE PRESSURE WOUND THERAPY (NPWT) IN DIABETIC FOOT WOUND IN TERMS OF WOUND SIZE REDUCTION AND WOUND BED PREPARATION FOR SECONDARY PROCEDURE

Protocol number and date: USM/JEPeM/18060276

By:

Dr Nor Hafizah binti Zarullail

(P-UM0167/16)

Master of Medicine (Orthopaedic) HUSM

(No MPM: 54437)

Supervisor:

Professor Dr Amran Ahmed Shokri

Lecturer, Arthroplasty and General Orthopaedic Surgeon, Department of Orthopaedic, HUSM

Introduction and Study Background

Over the past few decades, diabetes mellitus (DM) has emerged as one of the most prevalent chronic diseases worldwide. In Malaysia, a recent study reported that the overall prevalence of DM among Malaysians was 22.9% in year 2013, and 12.1% of them were newly diagnosed diabetics (1).

Diabetic foot is one of the major concerns of the complications of chronic diabetes and is defined as a foot affected by ulceration that is associated with neuropathy and/or peripheral arterial disease of the lower limb in a patient with diabetes (2). Diabetic foot complications result in increased hospital bed occupancy and account for increasing healthcare cost and resources (3). Ulceration, infection, gangrene and amputation are significant complications of the disease.

Diabetic foot ulcer (DFU) affects 15% of people with diabetes. The rate of diabetic foot increases year by year. In the National Health and Morbidity Survey 2006 conducted by the Health Ministry, 4-7% of known diabetics had undergone toe or leg amputations.

Diabetic foot ulceration is a major diabetes complication and its management involves a multidisciplinary approach. Proper treatment for diabetic foot ulcer can lower the risk of limb amputations (4).

Reconstruction of diabetic foot ulcers is often a challenging problem. The impairment of the healing process and the lack of resistance against infections in patients with diabetics represent a familiar clinical problem. The surgical treatment of the diabetic foot wounds with loss of soft tissue usually consist of closure using split-thickness skin grafts of transposition flaps. However, immediate surgical closure often fails because the general conditions of patient and wound may not be appropriate for surgical closure; therefore, initial steps consists of standard wound care (moist gauze dressing) to prepare the wound bed for final closure. This standard wound care will result in prolonged hospital stay thus increasing the hospital cost.

Negative pressure wound therapy (NPWT) was developed by Argenta and Morkywas to promote the healing of open wounds. In clinical and experimental studies, effects of the negative pressure are reported as increase of local blood flow, formation of granulation tissue and decrease bacterial colonization. The faster wound healing results in decreased hospitalization and avoidance of additional morbidity in chronic wounds. NPWT is a treatment that has become widely adopted for a broad range of wound indications since its advent over 15 years ago (6) . Supporting evidence for NPWT in the treatment of diabetic foot wounds includes numerous prospective and multi-centered randomized controlled trial (7).

Literature review

Diabetic foot ulcers were typically chronic wounds which were difficult to heal. This was due to a range of pathogenic abnormalities in diabetics which included ischemia and intrinsic defect of angiogenesis and impaired immunity against infection (12). Negative pressure wound therapy (NPWT) was developed by Argenta and Morykwas to promote healing of open wounds. In clinical and experimental studies, effects of the negative pressure are improve local blood flow, induce macrodeformation, induce granulation and angiogenesis, reduce edema and reduce bacterial colonization (7). The negative pressure provides a moist wound bed, which is required for faster healing of chronic open wounds. Faster wound healing during the treatment of diabetic foot ulcers may decrease hospital stay which in turn lower the cost of treatment and additional morbidity of infection and pain. Many studies have been done to prove the effectiveness of negative pressure wound therapy in the treatment of diabetic foot wound.

The negative pressure wound therapy (NPWT) group proportion was significantly (P=0.007) greater for complete ulcer closure than that for advanced moist wound therapy (AMWT) group. In assessing ulcer area, a significant difference between NPWT and AMWT

from baseline was achieved on day 28 (P=0.021). In terms of effect on wound bed preparation, NPWT and 114 days in AMWT (P=0.022) (8).

The early appearance of granulation tissue in group received negative pressure dressing was found to be statistically significant compared to group received conventional saline moistened gauze dressing. There was a statistically significant ($P< 0.05$) in terms of the mean decrease in wound size in patients with negative pressure dressing compared with conventional saline dressing. This study also observed that patients with negative pressure dressing showed rapid clearance of bacterial load as compared to saline dressing. Although statistically the time status of wound closure was comparable in both groups ($P>0.10$), it was seen that the patients in negative pressure dressing showed faster healing as compared to the conventional saline dressing (9).

Wounds treated with a 125 mmHg vacuum had filled with granulation tissue by day 8. At this time wounds treated with 25 mmHg had filled with 21.2% with new granulation tissue, and wounds treated with 500mmHg had filled 5.9% with new tissue. In conclusions, wound treated with a 125mmHg vacuum exhibited a significant ($p < 0.0001$) increase in the rate of granulation tissue formation compared with treatment at 25 mmHg or 500 mmHg (10).

Wound contraction and fluid removal increased gradually with increasing levels of negative pressure until reaching a steady state. Maximum wound contraction was observed at -75mmHg. When negative-pressure wound therapy was discontinued, after 72 hours of therapy, the wound area was smaller than before therapy. Maximum wound fluid removal was observed at -125 mmHg (11).

Blood flow changed gradually with increasing negative pressure until reaching a study state. At 2.5cm from the wound edge, blood flow increased 6% at -10mmHg, 32% at -45mmHg, and 90% at -80mmHg. Higher levels of negative pressure did not have additional blood flow effect ($p>0.30$). This study implies that -80mmHg has similar blood flow effects as the clinical standard, -125mmHg (12).

Justification of study

The conventional NPWT systems adopts either intermittent or continuous mode. In experiments performed on the animal models, it has been shown that the intermittent mode showed increased perfusion level and formation granulation tissue compared to continuous mode. Despite the effectiveness of the intermittent mode in wound healing, it has been avoided in clinical application because of the pain occurring every few minutes during the initiation phase to reach the optimal pressure. Thus the cyclic NPWT was introduced and it shows reduced in patient discomfort while maintaining superior wound healing effects as the intermittent mode (3). The cyclic NPWT system is similar to the intermittent mode in terms of using the same maximal subatmospheric pressure but the pressure never reaches zero in the cyclic mode. So, it continuously creates certain pressure gradient that oscillates between -125mmHg and the preset subatmospheric pressure. Since the introduction of the cyclic NPWT system which its pressure oscillates in between 2 pressure difference, we want to know which pressure is more effective. This study will use -50 mmHg as the low the pressure and -100mmHg as the high pressure as this level is within the recommended therapeutic range. Although the standard pressure for NPWT is -125mmHg, it is not used in this study because it is difficult to set pressure at -125mmHg using the suction wall regulator which will be connected to the vacuum source in ward. The goal of this study is to compare the effectiveness of low and high pressure negative wound therapy in term of wound size reduction and optimal wound bed preparation.

Research question

Low or high pressure is more efficient in negative pressure wound therapy for diabetic wound.

Main objective

To determine whether the low or high pressure in negative pressure wound therapy is more effective in term of wound size reduction and optimal wound bed preparation in patient with diabetic foot wound admitted to orthopaedic ward Hospital Universiti Sains Malaysia in between 1st of Dec 2018 till 31st of May 2019.

Specific objective

To compare the effectiveness of low or high pressure NPWT in the treatment of diabetic foot wound in terms of

- Wound size reduction.
- Optimal wound bed preparation for secondary procedure using wound bed score by Falanga et al.

Methodology

Research design

This is a single centre prospective interventional; randomized controlled trial, open label study involving patients attending Department of Orthopaedic, Hospital Universiti Sains Malaysia (HUSM) with diabetic foot wound with Wagner grade 2 to 4 who requires admission for surgical procedures and requires wound dressing postoperatively

Study area

The study duration is from 1st Dec 2018 until 31st May 2019. The location for the study will be in the Orthopaedic wards in Hospital Universiti Sains Malaysia (HUSM) involving patients fulfilling the inclusion and exclusion criteria.

Study population

1. Reference population - All patients with diabetic foot wound with Wagner grade 2 to 4 attending Department of Orthopaedic, Hospital Universiti Sains Malaysia (HUSM).
2. Source population - All patients with diabetic foot ulcers with Wagner grade 2 to 4 attending Department of Orthopaedic, Hospital Universiti Sains Malaysia (HUSM) who required admission for surgical procedures and postoperative wound dressing from 1st Dec 2018 to 31st May 2019

Inclusion criteria

- Type 1 and 2 Diabetes Mellitus patients attending Orthopaedic Department, Hospital Universiti Sains Malaysia

- All patients with infected diabetic foot ulcers requiring surgical procedures such as debridement, drainage or minor amputation with Wagner grade 2 to 4.
- Patients age more than 18 years old and above

Exclusion criteria

- Patients with peripheral vascular disease with ankle brachial systolic index below 0.5
- Patient with known immunosuppressive disease or on immunosuppressive treatments
- Patient with known severe cardiovascular, renal, endocrine or neurological diseases
- Patient with skin pathology such as eczema, psoriasis and fungal infection.
- Pregnancy

Withdrawal Criteria

- Patient that require another surgical intervention after first application of NPWT
- Patient who experience side effects from application of NPWT (i.e: intolerable pain, allergic reaction to the sponge used)
- Patient refused for second application of NPWT

Sample Size Estimation

Sample size was calculated using Power and Sample Size Software

α : 0.05

Power : 0.90

m1 : 16.14

m2 : 5.98

Sd1 : 13.04

Sd2 : 14.41

Thus the final sample size for this study is (2 x 29) = 58 subjects

Mean and standard deviation was based on previous study (7)

Sampling Method and subject recruitment

Patients with infected diabetic foot ulcers requiring surgical procedures will be approached post operatively during the study period. Patients will be invited to participate in this study after satisfying the inclusion and exclusion criteria and written informed consent will be obtained.

Research tool

Patients will be started on the designated negative pressure therapy post 24 to 48 hours post operatively. The NPWT will be done once every 5 days for duration of 10 days. Sponge will be used as wound filler. A drainage tube size 12 Fr will be inserted into the sponge and

connected to a vacuum source. The wound will then be sealed with transparent adhesive drape. The desired pressure can be controlled using suction wall regulator that will be connected to the vacuum source in ward. The suction regulator that will be used is the American Type Suction Regulator VRA-321 (-300mmHg) produced by the Acare Technology (ISO13485).

Model & Specification

	-760mmHg	-300mmHg	-160mmHg
w/o adapter	VRA-701	VRA-301	VRA-101
w/ Ohmeda	VRA-711	VRA-311	VRA-111
w/ BS	VRA-721	VRA-321	VRA-121
w/ PB	VRA-731	VRA-331	VRA-131
w/ AFNOR	VRA-741	VRA-341	VRA-141
w/ JIS	VRA-751	VRA-351	VRA-151
w/ DISS	VRA-761	VRA-361	VRA-161
w/ DIN	VRA-771	VRA-371	VRA-171
w/ barb adapter	VRA-781	VRA-381	VRA-181
w/ Chemetron	VRA-791	VRA-391	VRA-191
w/ CIG	VRA-7A1	VRA-3A1	VRA-1A1
w/ Oxequip	VRA-7B1	VRA-3B1	VRA-1B1

Data collection method

All patients will be approached postoperatively before wound inspections were done. All the patients will be randomized into either the treatment group with either -50mmHg or -100mmHg Negative Pressure Wound Therapy. Patients were given numbers 1 to 58 and randomization of the treatment was done using web-based software www.randomization.com.

Data collection sheets will be filled by the investigator where demographic data, current medical illness, duration of ulcers were taken. A baseline size of the wound will be taken with a clean, transparent flexible plastic sheet film over the wound. The wound perimeter will be drawn (the border between the wound floor and the peripheral epithelium) on the film with an indelible fine tipped marker. Area in mm2 are calculated by placing the film on a metric graph paper. A baseline wound bed score (13) will be given together with a baseline photography using a standard setting digital camera.

After 5 days on designated negative pressure, the wound size will be re-measured again with the technique described above. The wound bed scores will be given again as above and digital photography will be taken again. The same method procedure will be repeated after 10 days of treatment.

The wound size will be evaluated and the wound bed score will be determined before starting the dressings at 5 days and after 10 days of treatment. The difference in the wound size after 5 days and 10 days will be converted to percentage of wound size reduction. The wound bed score was based on Falanga et al 2006 (Figure 4.1). It evaluates 8 wound bed score parameters which are healing edges, black eschar, greatest wound depth or granulation tissue, exudate amount, oedema, peri- wound dermatitis, peri-wound callus or fibrosis and pink wound bed percentage. Each parameter is given score from 0 to 2. The maximum total score is 16 and the minimum score is 0 (Falanga et al. 2006).

Wound bed score (Falanga et al. 2006)

Characteristic	0	1	2
Healing edges	None	25%-75%	>75%
Black Eschar	>25% of wound surface area	0-25%	None
Greatest wound depth/granulation tissue	Severely depressed/raised compared to periwound skin	Moderate	Flushed/almost even
Exudate	Severe	Moderate	None/mild
Edema	Severe	Moderate	None/mild
Periwound dermatitis	Severe	Moderate	None/mild
Periwound callus/fibrosis	Severe	Moderate	None/mild
Pink wound bed	None	50-75%	>75%

Data Analysis and Expected Results

This study mainly analyse the mean percentage of wound reduction and the mean of wound bed scoring between -50mmHg NPWT and -100mmHg NPWT. Data will be collected from all variables will be entered and analysed using IBM SPSS Statistic Version 22.

Table 1: Percentage of wound size reduction at day 5

Group	Mean (SD)	Mean Difference	RM-ANOVA statistic	p-value
Low pressure (-50mmHg)				
High Pressure (-100mmHg)				

Table 2: Percentage of wound size reduction at day 10

Group	Mean (SD)	Mean Difference	RM-ANOVA statistic	p-value
Low pressure (-50mmHg)				
High Pressure (-100mmHg)				

Table 3: Wound Bed score at day 5

Group	Mean (SD)	Mean Difference	RM-ANOVA statistic	p-value
Low pressure (-50mmHg)				
High Pressure (-100mmHg)				

Table 4: Wound bed score at day 10

Group	Mean (SD)	Mean Difference	RM-ANOVA statistic	p-value
Low pressure (-50mmHg)				
High Pressure (-100mmHg)				

Study Proforma

Comparison between low and high pressure negative pressure wound therapy (NPWT) in diabetic foot wound

STUDY ID:

REGISTRATION NUMBER: CONTACT NUMBER:

AGE:

RACE:

GENDER:

MEDICAL HISTORY:

TYPES OF DIABETES:

DURATION OF DIABETES:

DURATION OF ULCERS:

EDUCATION LEVEL:

OCCUPATION

IS/WAS PATIENT A SMOKER: YES/NO

IF YES WHAT IS THE CONSUMPTION:

HEIGHT: RADIOGRAPHIC FINDINGS:

WEIGHT:

BODY MASS INDEX:

PERIPHERAL NEUROLOGICAL EXAMINATION:

ANKLE BRACHIAL INDEX OF AFFECTED LIMBS:

DIAGNOSIS:

WAGNER CLASSIFICATION:

TYPE OF SURGERY PATIENT UNDERWENT:

DATE OF SURGERY:

1ST ASSESSMENT

I. WOUND SIZE (REFER TRACE PAPER & GRAPH PAPER): mm^2

II. WOUND BED SCORES (FALANGA ET AL)

Characteristic	0	1	2
Healing edges	None	25%-75%	>75%
Black Eschar	>25% of wound surface area	0-25%	None
Greatest wound depth/granulation tissue	Severely depressed/raised compared to periwound skin	Moderate	Flushed/almost even
Exudate	Severe	Moderate	None/mild
Edema	Severe	Moderate	None/mild
Periwound dermatitis	Severe	Moderate	None/mild
Periwound callus/fibrosis	Severe	Moderate	None/mild
Pink wound bed	None	50-75%	>75%

TOTAL SCORE: ____/16

III. CULTURE & SENSITIVITY

2ND ASSESSMENT (AFTER 1ST CYCLE)

I. WOUND SIZE (REFER TRACE PAPER & GRAPH PAPER): mm^2

II. WOUND BED SCORES (FALANGA ET AL)

Characteristic	0	1	2
Healing edges	None	25%-75%	>75%
Black Eschar	>25% of wound surface area	0-25%	None
Greatest wound depth/granulation tissue	Severely depressed/raised compared to periwound skin	Moderate	Flushed/almost even
Exudate	Severe	Moderate	None/mild
Edema	Severe	Moderate	None/mild
Periwound dermatitis	Severe	Moderate	None/mild
Periwound callus/fibrosis	Severe	Moderate	None/mild
Pink wound bed	None	50-75%	>75%

TOTAL SCORE: _____/16

III. ALLERGIC/ADVERSE REACTION

IV. ANTIBIOTIC AND DURATION

V. PHOTOGRAPH

3RD ASSESSMENT (AFTER 2ND CYCLE)

I. WOUND SIZE (REFER TRACE PAPER & GRAPH PAPER): mm^2

II. WOUND BED SCORES (FALANGA ET AL)

Characteristic	0	1	2
Healing edges	None	25%-75%	>75%
Black Eschar	>25% of wound surface area	0-25%	None
Greatest wound depth/granulation tissue	Severely depressed/raised compared to periwound skin	Moderate	Flushed/almost even
Exudate	Severe	Moderate	None/mild
Edema	Severe	Moderate	None/mild
Periwound dermatitis	Severe	Moderate	None/mild
Periwound callus/fibrosis	Severe	Moderate	None/mild
Pink wound bed	None	50-75%	>75%

TOTAL SCORE: ____/16

III. ALLERGIC/ADVERSE REACTION