“THE ROLE OF VACUUM ASSISTED CLOSURE IN COMPLEX WOUNDS”

Dissertation submitted to

THE TAMILNADU DR.M.G.R.MEDICAL UNIVERSITY

In partial fulfillment of the regulation for the award

of the degree of

M.Ch., (PLASTIC AND RECONSTRUCTIVE SURGERY)

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CERTIFICATE

This is to certify that the dissertation entitled "**The Role Of Vacuum assisted Closure in Complex Wounds"** is a bonafide work done **DR. B.SENTHIL KUMARAN**, post graduate (2011-2014) in the Department of Plastic, Reconstructive & Faciomaxillary Surgery, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai – 03, in partial fulfillment of the University rules and regulations for award of **Master of Chirurgiae**, **Plastic & Reconstructive Surgery (branch III)** degree under my guidance and supervision during the academic year 2011-2014.

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DECLARATION

I solemnly declare that this dissertation **The Role Of Vacuum assisted Closure in Complex Wounds** was done by me in the Department of Plastic, Reconstructive & Faciomaxillary Surgery, Madras Medical College & Rajiv Gandhi Government General Hospital, Chennai-03 between 2011 and 2014.

This dissertation is submitted to **THE TAMILNADU DR.M.G.R. MEDICAL UNIVERSITY, GUINDY, CHENNAI-32** in partial fulfillment of the university requirements for the award of degree of **M.Ch. PLASTIC & RECONTRUCTIVE SURGERY**.

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CONTENTS

INTRODUCTION

Vacuum-assisted closure (VAC) is new in the armamentarium of managing wounds acute and chronic. Vacuum assisted closure also called negative pressure wound therapy is a procedure in which vacuum is used to enhance wound healing vacuum-assisted wound closure refers to wound dressing that uses pressure below normal continuously or intermittently to the surface of a wound. The negative pressure is maintained by an apparatus ,this promotes healing in various kinds of wounds. It also helps in wound debridement .Wounds heal best when the negative pressure is 125 mmHg. Negative pressure removes fluid, decreases edema and increases blood flow. Thus decreasing bacterial counts. The technique is less expensive than conventional management of complex wounds.[1]

The technique is relatively simple. sterile, porous foam dressing is directly placed on the wound. The wound is then closed with a sterile adhesive sheet in order to create a closed area. A tube is connected to a vacuum pump,fluid is sucked through the foam into a canister which is discarded. Negative pressure of 50-125 mm/Hg, results in the lowering of interstitial pressure, and fluid

and debris from the wound is sucked into a collection chamber. In the begining, the vacuum is continuous . As the drainage decreases, the vacuum is applied intermittently. The vacuum dressing is usually changed at approximately two day interval. [2, 3]

Wound progress is recorded using parameters in the wound scoring system. The objectivity of assessments used to mark the wound score make this scoring system deal for evaluating treatment and outcome of wounds. And effectiveness of this treatment is established and proven by this objective scoring system.

OBJECTIVES OF THE STUDY

1. To study the outcome of vacuum assisted closure of wounds.

2. To evaluate the positive impact of vacuum assisted closure on wound healing in enhancing granulation tissue formation.

REVIEW OF LITERATURE

INTRODUCTION

A wound is defined as a break in the skin or mucous membrane or tissue caused by trauma , chemical or biological injury.

John Hunter said , ". . . the injury alone has in all cases a tendency to produce the disposition and the means of a cure."

Pare said , a surgeon's aim in wound management is to create a friendly environment where wound healing can proceed in an optimal fashion. Which require sepsis free ,devoid of fluid accumulation and vascularity and oxygen supply.

Wound healing is a fundamental hemostatic process in response to injury. It involves the activation of basic cellular process of inflammation, cell proliferation, and cell growth as well as regeneration of these processes once repair is complete.

NORMAL WOUND HEALING

The body responds to injury by healing . Stages of wound healing are presented as discrete events, however do not occur independently and overlap each other in a significant way.

Emphasis is on the underlying physiologic process and the pattern of responses with surgical dressings. Every tissue undergoes repair after injury. Only bone heals without scar.

The **STAGES OF WOUND HEALING** takes place in an overlapping and sequential manner

- Coagulation
- Phagocytosis
- Chemotaxis
- Mitogenesis
- Collagen Synthesis
- Extracellular Matrix Synthesis
- Contraction

WOUND HEALING PHASES

1. Hemostasis and inflammatory
2. Proliferative
3. Maturation and remodeling

INFLAMMATORY PHASE

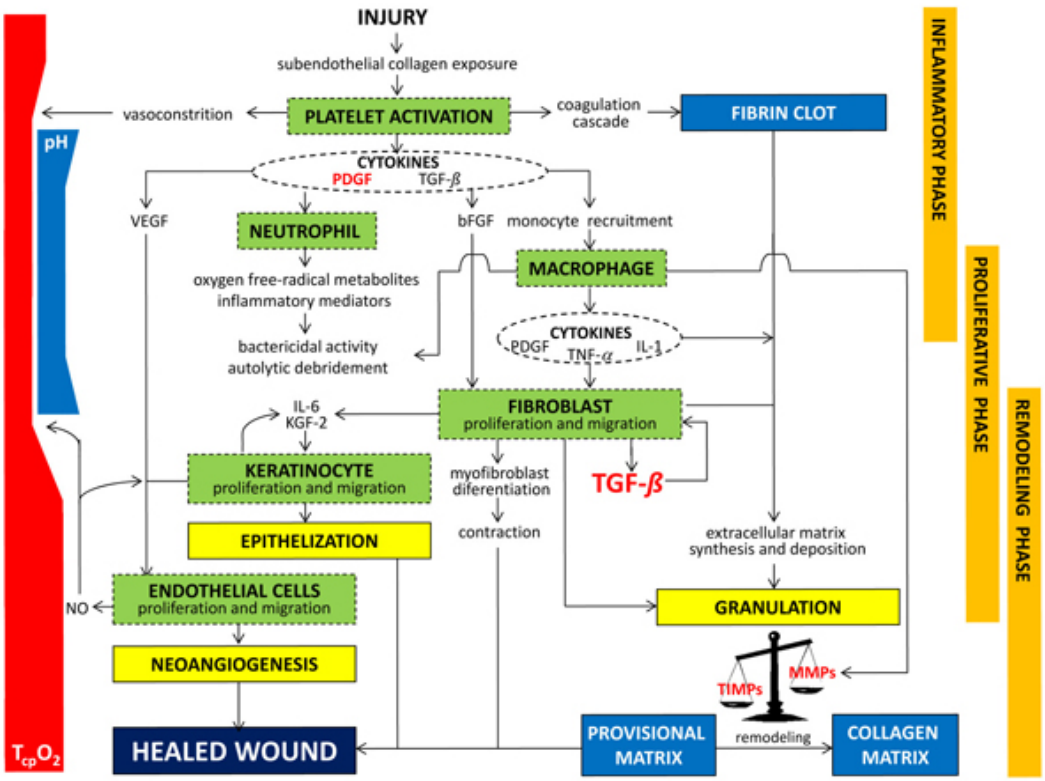
Soon after injury, The inflammatory phase begins. The first response is the disruption of blood vessel ie bleeding. The hemostatic response is clot formation . Platelet plug formation begins the cascade of hemostatis along with clotting factors which is activated by the exposed collagen and basement membrane .

After injury, vasoconstriction is mediated by catecholamines, thromboxane and prostaglandins (PGF2). Platelets degranulate, into the extra cellular space, provides the alpha granules and dense granules, chief among them is the platelet derived growth factor (PDGF) and also the transforming growth factor beta (TGF beta). These substances start chemo taxis and inflammatory cells proliferation, beginning the inflammatory response that will finally heal the wound.

Vasoconstriction which is transient decreases blood at the time of the initial trauma and also to allow the formation of clot. Active bleeding stops once a clot has been formed and vasodilatation increases blood flow to the wound , which supplies cells and substrate needed for further wound repair. The deformation of vascular endothelial cells increases the permeability of vessels.

At this stage, the wound is laden with debris from the injury. It contains

1. Devitalized fat, muscle and other tissues
2. Fibrin mixed with platelets, erythrocytes -clot
3. Bacteria
4. Extra vasated serum proteins
5. Foreign bodies



PROLIFERATIVE PHASE

This starts as a provisional matrix of fibrin and fibronectin which is a part of the initial clot process.Due to the growth factors Fibroblasts proliferate and becomes the dominant cell type in this stage. Macrophages produce Growth factors which induces angiogenesis, which in turn stimulates the in growth and multiplication of endothelial cells, to form new capillaries. Neovascularation is seen through the epithelium and this gives the wound a pink or purple red look. Capillaries nourish the fibroblasts with nutrients and oxygen to increases cell proliferation and the production of the permanent wound matrix. This matrix is made of

collagen and proteoglycans as ground substance and replaces the temporaryl fibronectin-fibrin matrix.

The four important events in proliferative phase are

- Angiogenesis
- Fibroplasia
- Epithelialization
- Contraction

ANGIOGENESIS

It is the process of new blood vessel formation, angiogenesis is orchestrated by macrophages during the inflammatory phase.

Angiogenesis occur by the following process

Disruption of the basement membrane of post capillary veins with movement of cells through this gap which is because of the action of FGF, PDGF, and TGF-β. PECAM-1, is a factor which modulates their inter action with one other as they move into the wound is also from endothelial cells.

Tubule or lumen formation involving cell-cell and cell-matrix interactions. Budding capillaries transform into arterioles and venules, others undergo involution and apoptosis, which are then ingested by macrophages.

Deposition of the basement membrane resulting in capillary maturation

FIBROPLASIA

This begins with the destruction of the fibrin-platelet provisional matrix.

Replacement ECM is made and deposited in the wound site by fibroblasts,this occurs during fibroplasia phase. In a clean uninfected wound by day 3-5 fibroblasts multiply to become the predominant cell type. The fibrin matrix is removed and is replaced by a provisional matrix of fibronectin and hyaluronic, this facilitates the movement of fibroblasts. Resting mesenchymal cells in connective tissue specializes into cells that differentiate . These do not arrive in the wound by diapedesis from circulating cells. The quiet and few fibroblasts move by chemotaxis into the wound then divide and synthetize the components of ECM soon after injury . The fibroblasts arrests at G0 phase, then multiplies and proliferates after being stimulated by macrophages , platelet-derived cytokines and growth factors. During the time between injury and appearance of collagen the undifferentiated mesenchymal cells differentiates into highly specialized fibroblasts.

EXTRA CELLULAR MATRIX

Surrounding the ECM, cells becomes big, migrate, and differentiate in intimate contact with macro molecules. Secreted on site and distributes into a network between the spaces surrounding the cells.

Functions of ECM:

Matrix protein sequester water that provide turgor to soft tissue and minerals that give rigidity to skeletal tissues.

Reservoir for growth factors controlling cell proliferation

Provides interaction between cells and stratum for cells to stick, migrate and multiply.

ECM consists of

1. Structural proteins viz collagen and elastins

2. Glycoproteins or cell adhesion molecules

3. Basal Lamina

4. Proteo glycans and hyaluronic acid

GRANULATION TISSUE FORMATION

The loose temporary matrix of fibronectin, hyaluronic acid and collagen house the dense mix of blood vessels, macrophages and fibroblasts . Clinically this is the meaty red proud flesh which is present in open wounds. It is due to the increased bed of fresh formation of capillary networks formed by endothelial division. The platelets and activated macrophage and fibroblast provide the direct growth of vascular endothelium . The clinical indicator that an open wound is fit for skin grafting is this granulation tissue.

EPITHELIALIZATION AND CONTRACTION

Epithelization occurs in closed surgical wounds. Contraction occur in open wounds the surrounding skin is pulled all around toward the center of an open wound. The wound size decreases dramatically and the wound is closed quickly without the formation of new tissue quickens the wound closure. The contraction of wound is related to both the size of the wound and skin mobility.

Wound contracture is greatest in the trunk and perineum, least seen in the extremities, and less in the head and neck.

Mechanisms for wound contraction are not clear.

1. Myofibroblasts generate contractile forces, Myo fibroblasts are fibroblasts that contain smooth muscle in their cytoplasm.

2. Membrane metalloproteinases is important necessity for wound contraction. Stromelysin-1 (MMP-3) affects wound contraction by cleaving the attachment between the fibroblast and the collagen so that the contraction of lattice can occur.

Wound contraction is different from wound contracture.

The basal cells in the wound edge provide the new epithelial cells for closure of wound . The epidermis thickens and basal cells move over the wound these keratinocytes move donot divide till it is continous with the other fellow ,daughter cells move as a sheet by tumbling and leapfrogging .this movement is orchestrated by glycoprotiens viz tenascin and fibronectin .After the laying of epithelium, the fibroblasts and Keratinocytes produce collagen type

4 and laminin ,keratinocytes restores the epidermis and the barrier is reformed.

The cells which migrate divides and seperates the eshar from the living tissue. Epithelization is quick if the basement membrane is intact.otherwise the basement membrane will be repaired first, the cells become columnized and stratified again and gets attached firmly to the basement membrane below.

REMODELING PHASE

The ECM undergoes remodelling constantly as it is dynamic. The ECM is strengthened by cross linking of collagen and wound tensile strength is improved Lysyl oxidase collagenases, gelatinases and matrix proteinase take part in remodelling.

Scar formation is the final result of wound repair . The collagen is densly packed in the scar and not as reticular in normal skin. .Scar has no hair follicles and sebaceous glands and has a collagen pattern that is completely different from the normal skin.

Mature scar takes many months to a year to form as remodelling occurs. The scar initially appear red due to the dense capillary network . Scars become hypo pigmented after full

maturation in white races .They are hyper pigmented in darker races and in lighter patients who receive prolonged sun exposure.

FACTORS WHICH AFFECT WOUND HEALING

Local :-

O technique

O vascularity

O stress

O movement

O extent

O bleeding

O foreign particles

O edema

O irradiation

O suture material

O wound infection

Systemic factors:-

- o Age
- o Obesity
- o Malnutrition
- o Hypovitaminosis
- o hypoxia
- o Diabetes

CLINICAL IMPLICATIONS

Atraumatic handling of tissue decreases non-viable cells at the margins of the wound

Fat does not contain collagen and does not hold tension. Therefore, fatty tissue should not be sutured as a separate layer.

Dead space obliteration and fluid evacuation are best achieved by suction drainage rather than adding additional foreign material to the wound in the form of suture material

Under normal circumstances, epithelialization of an incision is complete within 24 to 48 hours, and there is no reason to protect the incision from water beyond this time.

Allowing patients to wash or shower 1 or 2 days after surgery has significant psychological benefit and gently debrides the incision and keeps it clean by rinsing away surface bacteria and debris.

Showers reduce the chances of bacterial accumulation in surface crusts along the incision and on sutures. This decreases inflammation and prevents breakdown of fragile epithelial layer over incision, improving the quality of the scar. [6]

Wounds are wide in distribution and they pose a serious problem in the community. they compromise patient mobility and are time consuming in treating. The wounds may be associated with a large number of medical, surgical and dermatological conditions and their origin is multifactorial. Wounds are of various etiologies and are on the increase in part with the increased incidence of variety of associated diseases like diabetes mellitus, arterial diseases, venous diseases, metabolic diseases, neoplastic conditions, etc. [7]

Wounds are classified frequently as acute or chronic.

The duration of Acute wounds are less than 8 weeks not yet completed the wound healing cycle. Chronic wounds are

wounds that have failed to complete the orderly and timely process that produces anatomic and functional integrity (Lazarus, Cooper, Knighton, et al., 1994). Chronic wounds take a long time to heal , do not heal fully , or that which recurs . [8]

CLASSIFICATION AND CAUSES OF WOUNDS

1 Traumatic

- Radiation
- Thermal Burns
- Decubitus
- Mechanical

2. Vascular

- Arterial
- Atherosclerosis
- Vasculitis
- Buerger Disease
- Raynaud Disease

Venous

- Chronic venous insufficiency
- venous ulcers
- Post Sclerotherapy ulcers
-

Lymphatic

- Chronic Lymphedema

3. Infective

- Pyogenic
- Gangrene
- Tuberculosis
- Fungal Infections

4. Neoplastic

- Squamous cell ca
- Basal Cell Ca
- Melanoma
- Kaposi's Sarcoma

5. Systemic

- Diabetes
- Ulcerative Colitis
- Sickle Cell Disease

6. Neurotrophic

- Spinal Cord Lesions
- Diabetes
- Syphillis
- Peripheral Neuropathies
- Alcoholism

MANAGEMENT OF WOUNDS

Wound healing begins with the clearing of debris and reigning infection. It then proceeds in a highly orchestrated manner. As soon as Inflammation cleans the wound angiogenesis (new in growth of vessels) causes to increase blood supply to the wound . The wound then heals by the deposition of granulation tissue, the wound later wound contracts and matures. When any one of this fail the wound does not heal fully. There are other agents such as pressure, increased levels of blood sugar, venous insufficiency, vasculitis and long periods of immobilisation which alters wound healing. [9]

The common principles of treatment of management of wounds, which includes wound debridement of devitalised tissue, keeping the wound moist and infection control. The treatment of the wound depends on the wound type,the clinical makeup of the patient. The basic principles of wound healing is then applied [10] . Wound can be treated at home or in a specialized wound treatment centers. Many of the chronic wounds can actually heal with intelligent and optimal care.

The past history of wound care is a variable factor for clinical trials, and this is a concern as variability contributes to the heterogenecity.

Initial surgical management is wound debridement. This removes devitalized tissues effectively [11] , then the wound is kept wet-to moist (WM) by gauze dressings, which is changed twice a day (Joseph 2000). These dressings are relatively cheap, available readily and simple to use. Vacuum-assisted closure is an alternative method that enhances wound healing with fewer dressing changes. Vac is useful in complex chronic wounds

VACUUM-ASSISTED CLOSURE

Vacuum-assisted closure is a alternative method for treating of chronic wounds. Negative pressure is used to aid wound healing. Negative pressure removes fluid and debris from the wound, thus removing the base needed for microorganisms to thrive. Negative pressure also increases angiogenesis and accelerate the formation of granulation tissue . (Lionelli and Lawrence, 2003) The cells are stimulate mechanically by negative pressure thereby causing the cells to proliferate and increase protein systhesis .[12]

In 1993 Dr Michael Morykwas and Dr Louis Argenta were the first to use VAC (Rosser et al. 2000). It is a offshoot of vacuum-assisted drainage to remove serous fluid and blood from the operated site post operatively so that there is a dry surgical field and prevent collection of seromas and hematoms (Thomas 2001). By using VAC the negative pressure (vacuum) clears blood and serous fluids from the wound, this reduces infection (closed/sealed system is a hypoxic environment) and improves blood flow, thereby the wound gets increased oxygen and nutrients which promotes healing.

Nomenclature of VAC varies, it can be topical negative pressure(TNP), or sub-atmospheric pressure, or sealed surface wound suction, or vacuum sealing and foam dressing (Vacuum therapy in wound management 2001). [13]

Negative pressure wound therapy (NPWT) uses negative pressure or suction to remove fluids, infectious an infective materials and debris from the wound. This promotes the formation of healthy granulation tissue. An NPWT device is applied tothe wound after removing necrotic tissues and cleaning dirty wounds. [14]

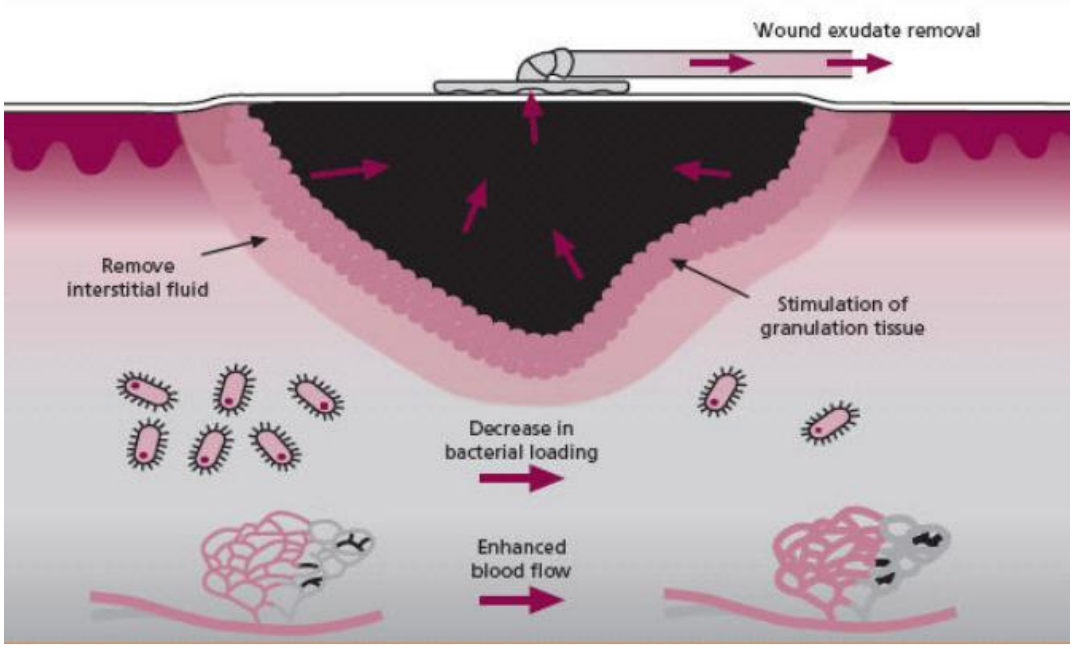
The exact mechanism is not clear, it is said that negative pressure helps in wound healing by the removal of interstitial fluid, increase in the wound vascularity, and the mechanical forces which pull the edges of the wound closer.

The technique is simple and involves the application of sterile, porous foam directly on the wound. The wound is sealed with an adherent drape which creates a closed, controlled environment. A perforated tube is placed over the foam and connected to a canister . Negative pressure is then applied at 125mmHg, which results in a decrease in the interstitial pressure, and fluid from the wound is sucked into the canister. The negative pressure is applied continuous manner initially . When the drainage decreases, the negative pressure can be on a intermittent basis. The foam dressing is changed at 48-hour interval. [15, 16, 17]

MECHANISMS OF ACTION OF VAC

Whe the wound edges are approximated by suturing the wounds heal by first intention or primarly. When the wounds are not approximated it heals by secondary intention.Here a matrix of neo blood vessels and fibroblasts forms in between for keratinocytes to migrate across the wound and reepithelialise the soft tissue defect. It is a complex, process. The aims of which is

decreasing blood loss by vasoconstriction and clotting, replacing defects with granulation tissue and restoring an epithelial barrier quickly . To achieve this debris is removed , infection controlled and inflammation reduced.The wound heals by granulation tissue , connective tissue matrix remodels and then matures finally. The wound healing rates is limited by blood supply and the ability of the wound to form neo capillaries and matrix. Disruption of any one of the processes involved Viz proliferation, chemotaxis, migration, angiogenesis, protein production leads to a chronic non healing wound. VAC ensures a controlled environment for wounds and, hence therefore, adheres to the precautions.



LOCAL BLOOD FLOW

Doppler flowometry by Morykwas showed that negative pressures of 125 mm Hg resulted in an increase in blood flow by four times. He used a wound model in pigs. This increase is also noted in human burn injuries . But when the pressures are increased to 200 mm Hg blood flow decreased . whether increasing pressures leads to an eventual decline in blood flow or in a cyclical pattern is not known and is confusing.[18]

These effects on skin vasculature are brought out by vasomotor mediators.. However, the mechanical forces exerted on the extracellular matrix ECM inevitably affects the microvasculature within. Vacuum Assisted Closure (VAC) is used in wound healing and has been shown to increase angiogenesis. [19]

Mechanical stress

The physical forces in negative pressure therapy is theoretical however evidence shows the importance of mechanical stress on reproduction of cells and angio genesis [20] . Increase in mechanical stress in vitro leads to an increase in cellular activity, which varies depending on cell types and methods used. Rapid cell cycling and DNA/protein synthesis is reported. Evidence shows that mechanical forces increase fibrogenesis in wound models. [21,22]

Granulation tissue formation

Morykwas studied by creating dorsal full thickness wounds in the midline in pigs Impressions using alginate was taken daily after treatment with VAC . The casts showed that VAC treated wounds showed more granulation tissue formation when compared with the controls by 63% and 103.4% (continuous and intermittent suction), though the effect contraction played to the size is not known. The increase in the formation of granulation tissue is confirmed by Joseph and Fabian et al by using rabbit ear . [23,24]

Wound colonization

Pig wounds inoculated with Staphylococcus aureus from humans and a Staphylococcus epidermidis taken from pigs, which was then were treated with VAC or moist saline dressing showed a quick decrease in bacterial levels in the VAC treated wounds. [26,27]

Exudate management

VAC removes lots of fluid from wounds especially in burns [28] . The reduction in edema leads to an increase in blood and nutrient flow to the wound. However, even when the blood flow is not increased the aspiration of fluid from the wound and edema from the tissues encourages the movement of nutrient in the wound.[29,30]

As the fluids are removed buildup of mediators of inflamation is prevented this helps in the diffusion of nutrients into the wound. This is very beneficial in chronic wounds where the imbalance of metalloproteinases can lead to poor wound healing. The volume decreases in three to four days thereby decreasing edema. But there is no quantitative evidence to support the reduction in interstitial wound fluid. Studies are being done to evaluate changes in wound fluid after VAC.

INDICATIONS

The indications for using VAC are:

- Traumatic wounds
- Decubitus ulcers
- Chronic wounds
- Venous ulcers
- Diabetic ulcers
- Flaps
- Grafts
- Dehised surgical wounds

CONTRAINDICATIONS

- Fistulas to bowel /cavities
- Eshar
- Untreated Osteomyelitis
- Malignancy
- Bleeding Wounds
- Coagulation Disorders

The VAC system was criticized for being expensive However studies by Flack et al show that VAC therapy is less expensive and more effective other forms of dressing dressings. [31]

VAC has better wound healing than routine methods, with much less serious complications. With proper training and usage, VAC is easy to use and is a good alternative for the management of wounds.

SEQUENCE OF PROCEDURE:

1. Preparation of wound.

Old and soiled dressings are removed . A swab is taken for culture. Wound is irrigated with normal saline. Slough is surgically removed (surgical debridement) and haemostasis ensued. The peri-wound skin is prepared and ensure that it is clean and dry.

2. Placing the Foam

Foam dressing which is sterile is cut to the shape of the wound placed into the wound cavity. Foams are very effective in transmitting mechanical forces and evenly distributes negative pressure over the wound bed . Tube is placed over the foam and is connected to a microprocessor controlled suction pump that contains a collection jar.

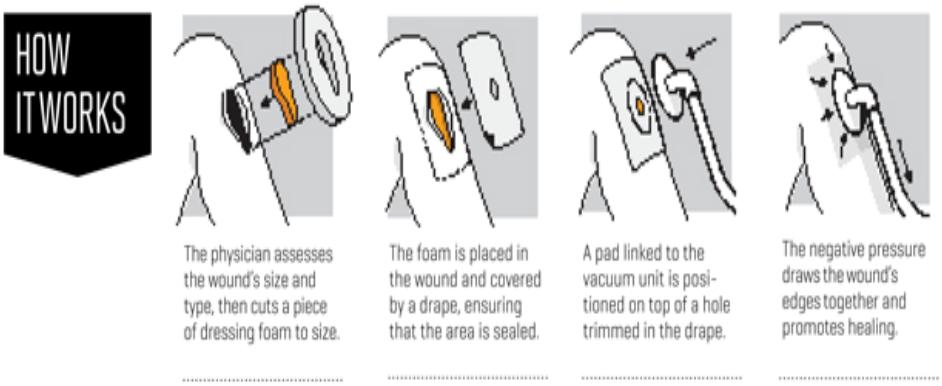
3. Drapes

The Wound is then securely closed with an adhesive drape. Drapes covers the foam and tubing and surrounds about five cm of healthy skin to create a seal, dressings should be changed every 48 hours or earlier if the wound is dirty and infected. When removing the adhesive drape injury to peri wound skin should be avoided . Nomal saline should be used to loosen the foam from bed.

4. Negative Pressure application

Negative pressure is uniformly applied to all tissues inside the wound (McCallon 2000). The foam dressing should compress and squeezes itself to the negative pressure. The pump delivers continuous or intermittent pressures, which ranges from 50 to 125 mmHg. The pressure is usually continuous for the first 48 hours and then changed as required. Intemittent delivery consists of a cycles

of seven minutes 2 minute off and 5 minute on . Ideal pressure is 125 mm hg but for wounds of leg and pressure wounds 50-75 is enough.



MATERIALS AND METHODS

SOURCE OF DATA

- Inpatients of Rajiv Gandhi Govt General Hospital
- Method of collection of data
- A total of 50 cases clinically presenting as ulcer between January 2011 and July 2012 were included in the study.

INCLUSION CRITERIA

Patients presenting with Wound

EXCLUSION CRITERIA

- Patient with Bleeding disorders
- Untreated osteomyelitis
- Bleeding wounds
- Patients diagnosed as malignancies.
- Clinical examination of each case was done systematically as per the proforma drafted for the study

PROCEDURE:

Preparation of the wound:

Dressings from the wound is removed . A swab for culture is taken. Wound irrigated with normal saline. Surgical debridement is done and adequate haemostasis achieved.

Foam Placement:

Foam dressing is cut to shape and kept into the wound cavity. The wound is then sealed with an adhesive dressing ensuring that the drapes cover the foam and tubing and at three centimeters of healthy skin.

Negative pressure application:

Negative pressure is applied to the wound using vacuum pump, which delivers continuous or intermittent pressures, ranging from 50 to 125 mm Hg. The foam dressing squeezes to the negative pressure. The pressure is continuously for the first 48 hours and changed.

The outcome was measured using wound scoring system consisting of area of wound covered with granulation tissue, and its color and consistency.

Statistical methods used

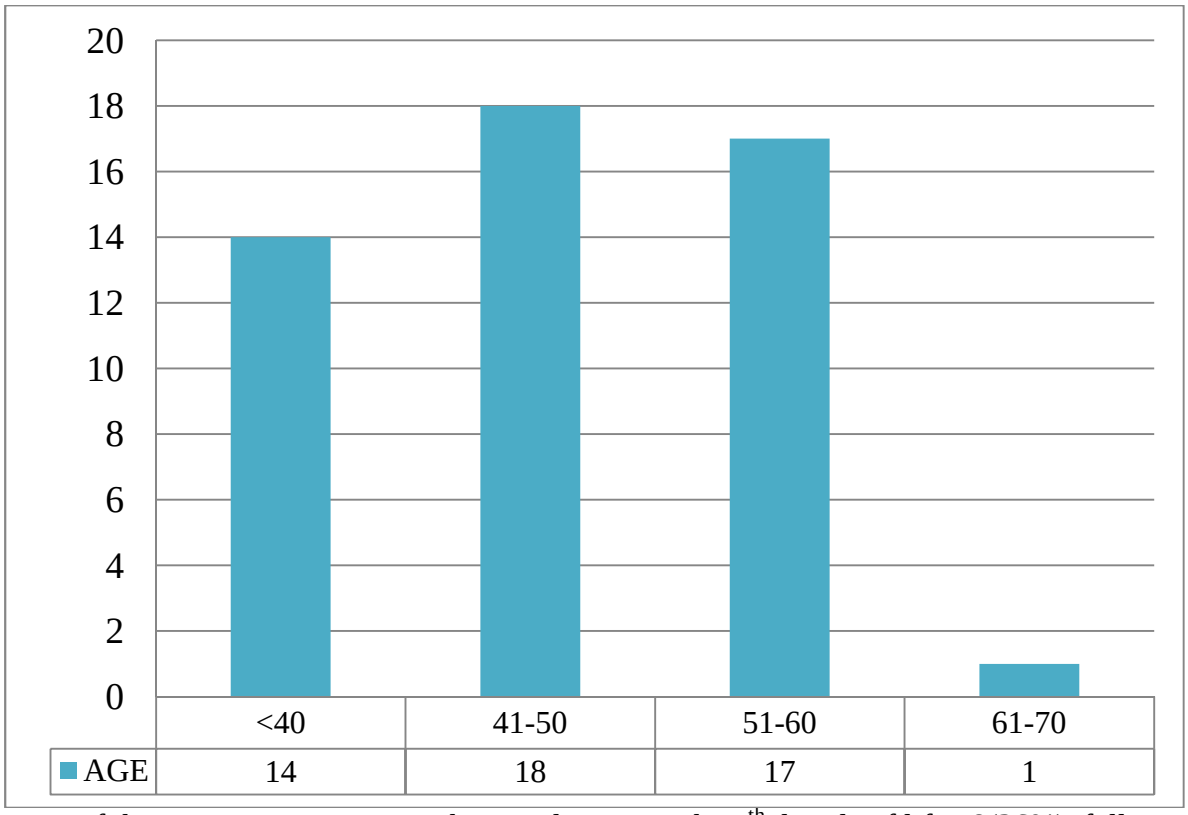
1. Frequencies
2. Mann-Whitney U Test
3. Kruskal-Wallis Test
4. Crosstabs
5. Chi-Square Test

All the statistical calculations were done through SPSS 16.0 for windows.

RESULTS

This study was done on fifty patients in the Department of Plastic Surgery, Rajiv Gandhi Government General Hospital, Madras Medical College, Chennai.

CHART 1: AGE DISTRIBUTION OF WOUNDS



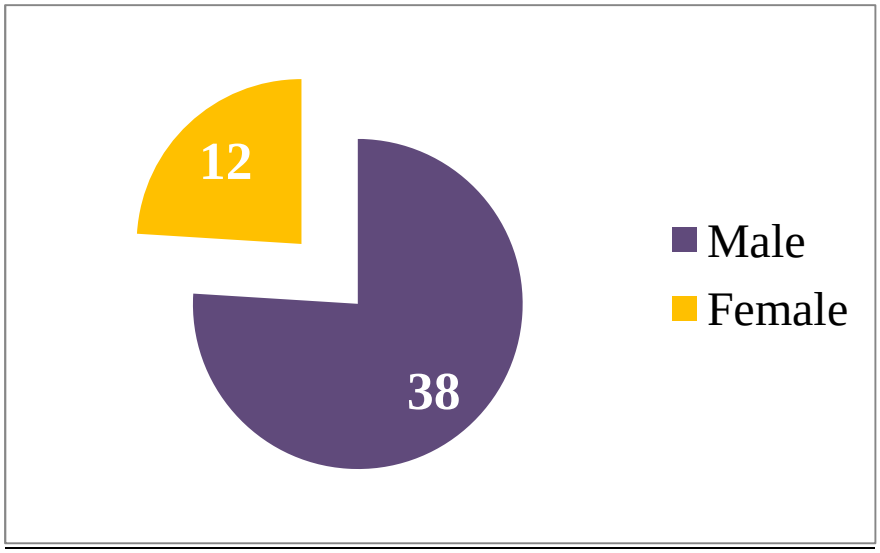
Most of the patients presenting with wounds were in the 5th decade of life 18(36%), followed by the 6th decade 17(34%).

TABLE 1:AGEWISE EVALUATION OF WOUND HEALING SCORE ON DAY 7

Age in years		Day 7		
	N	Mean	SD	Median
<40	11	5.09	0.94	5
41-50	15	4.73	1.22	5
>50	15	4.87	1.06	5
Total	41	4.88	1.08	5

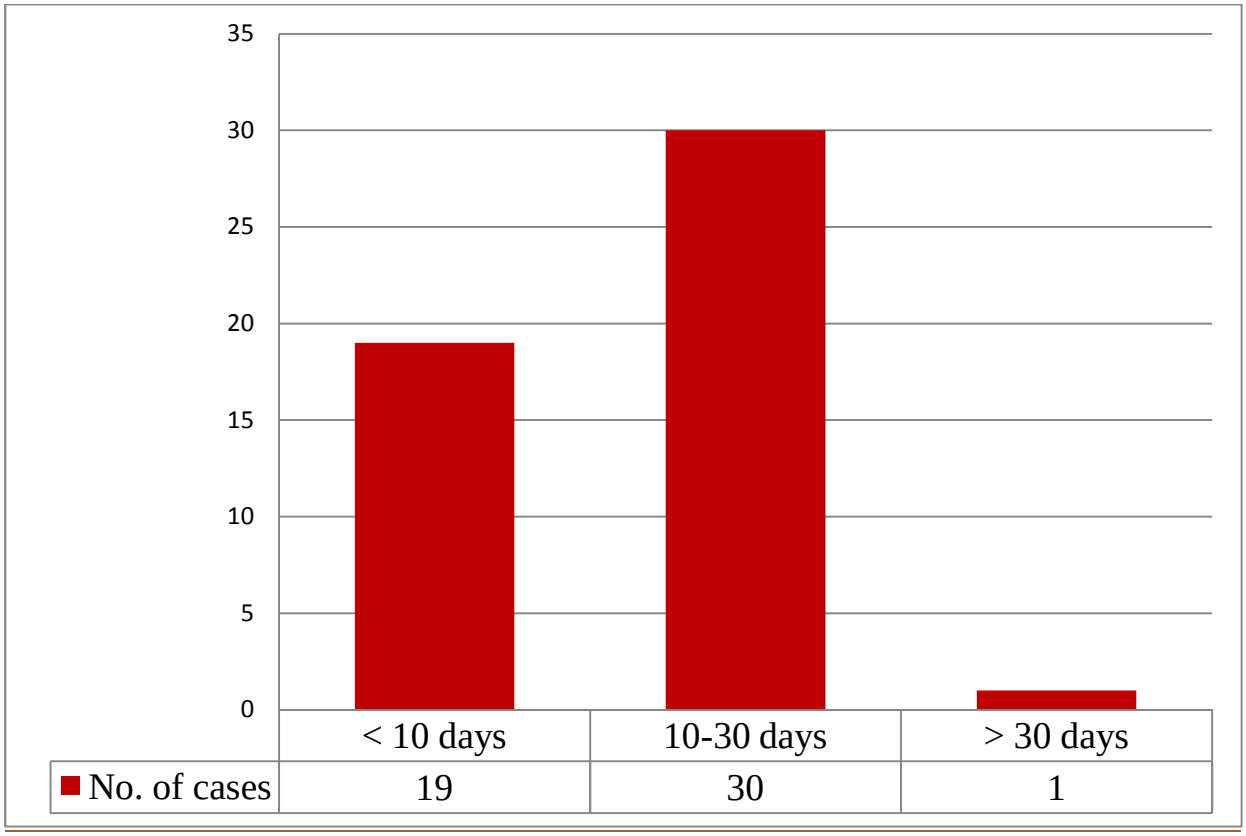
Kruskal wallis test, p=0.8

CHART 2: GENDER DISTRIBUTION OF WOUNDS



Wounds were more common in males 38 cases (76%) than in females 12 cases(24%) Male to female ratio 3.167: 1.

CHART 3: DURATION OF WOUNDS



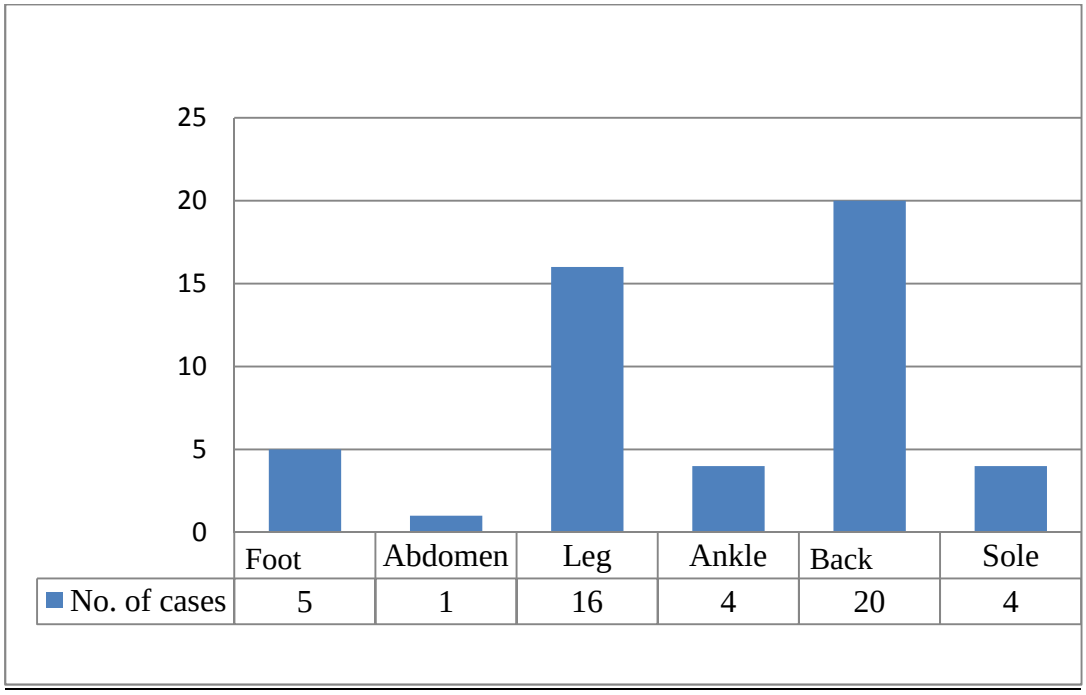
Based on the duration of wounds, cases were grouped into 3 categories: <10 days, 10-30 days and >30 days.
Most cases fall in the group 10-30 days 30(60%), 19 cases(38%) in the group <10 days and 1 case (2%) in the group > 30 days.

TABLE 2: DURATION OF WOUND - EVALUATION OF WOUND HEALING SCORE ON DAY 7

Duration in years		Day 7		
	N	Mean	SD	Median
<10 days	16	4.94	0.85	5
>10 days	25	4.84	1.21	5
Total	41	4.88	1.08	5

Mann whitney test, p=0.7

CHART 4: DISTRIBUTION OF LOCATION OF WOUNDS



Wounds were commonly located in the back 20(40%) followed by leg 16(32%) foot 5(10%) and ankle and sole 4 (8%) each. One patient had wound in the abdomen.

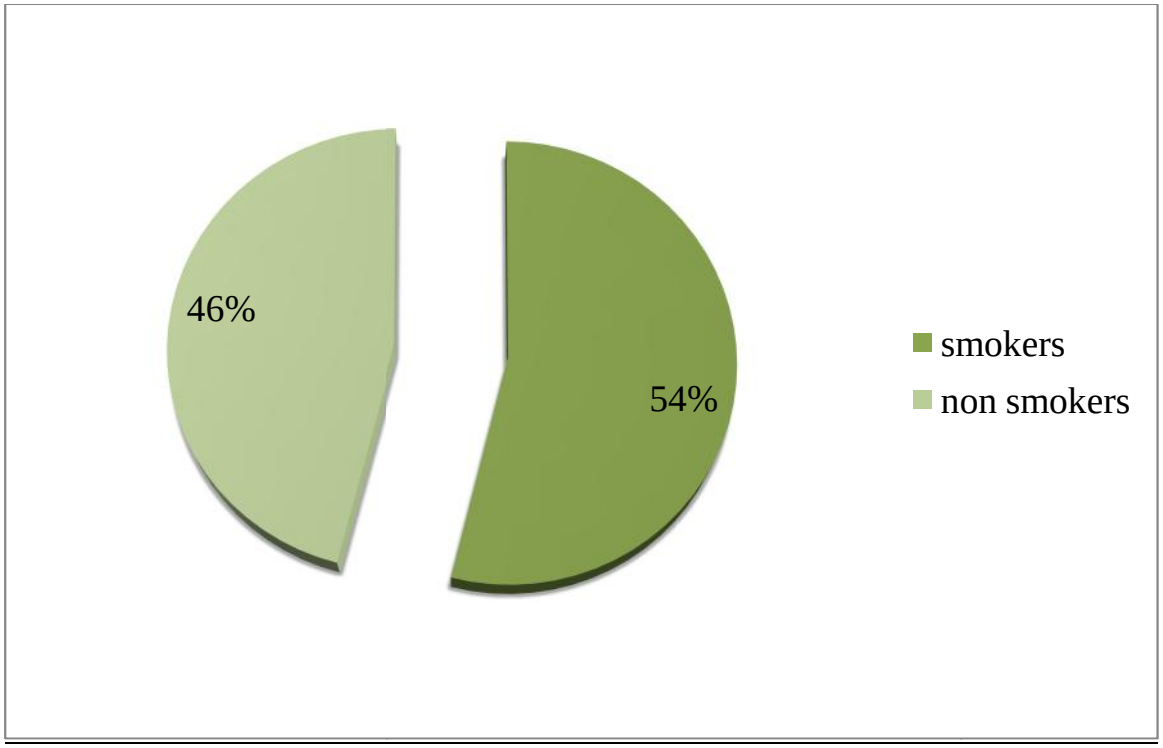
TABLE 3: LOCATION OF WOUND - EVALUATION OF WOUND HEALING SCORE ON DAY 7

LOCATION	Wound score					
	3.00	**4.00**	**5.00**	**6.00**	**7.00**	**Total**
FOOT	0	2	3	0	0	5
ABDOMEN	0	0	0	0	1	1
LEG	1	2	7	4	0	14
ANKLE	1	0	1	1	0	3
BACK	2	5	2	5	1	15
SOLE	1	0	2	0	0	3
TOTAL	5	9	15	10	2	41

P value – 0.024

Significant difference in wound healing depending on the location of the wound. P value-0.024

CHART 5: SMOKERS AND NON-SMOKERS



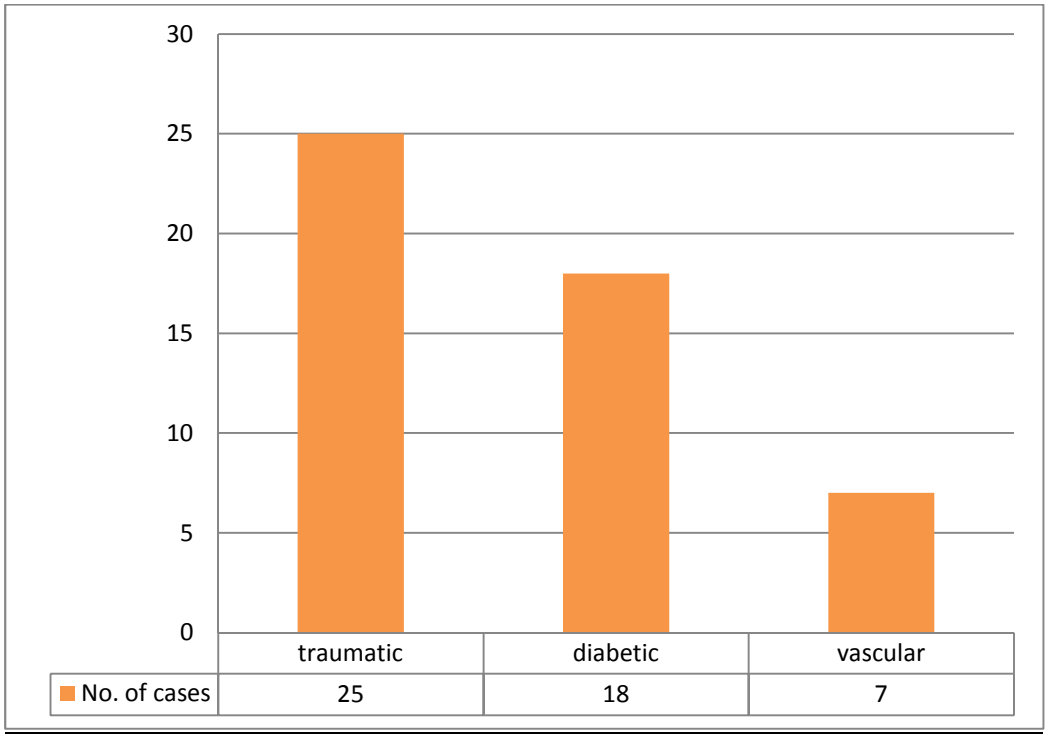
27 (54%) of cases were smokers, 23 (46%) were non- smokers.

TABLE 4: SMOKING - EVALUATION OF WOUND HEALING SCORE ON DAY 7

Smoking		Day 7		
	N	Mean (18)	SD	Median
Yes	24	4.50	0.89	5
No	17	5.41	1.12	6
Total	41	4.88	1.08	5

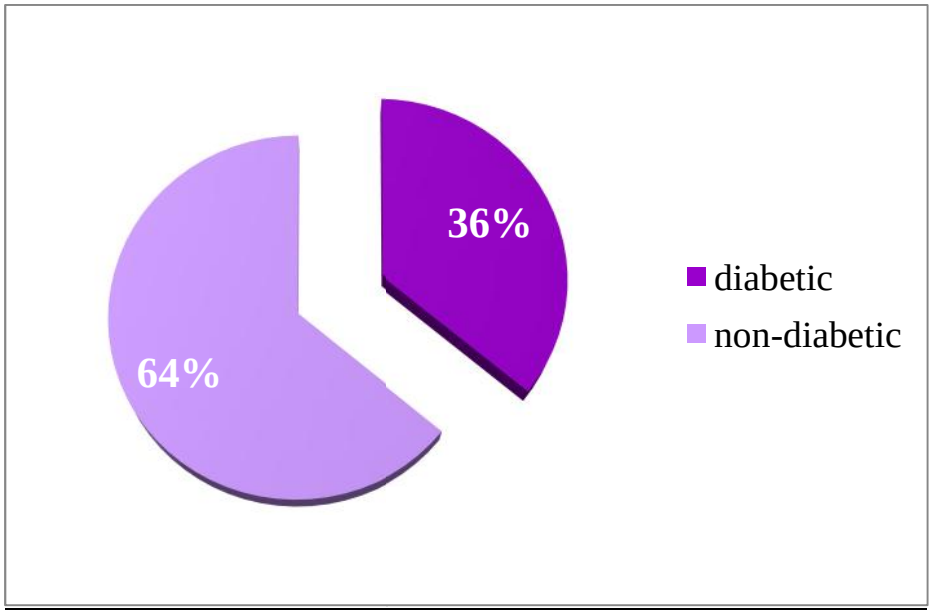
Mann whitney test, p=0.006

CHART 6: ETIOLOGY OF WOUNDS



Based on etiology of wounds, which were determined by history and clinical examination, wounds were divided into Traumatic, Diabetic and Vascular.
A major portion 25(50%) of cases fell into traumatic group and 18(36%) into diabetic and 7 (14%) into vascular group.

CHART 7: DIABETIC AND NON-DIABETIC WOUNDS



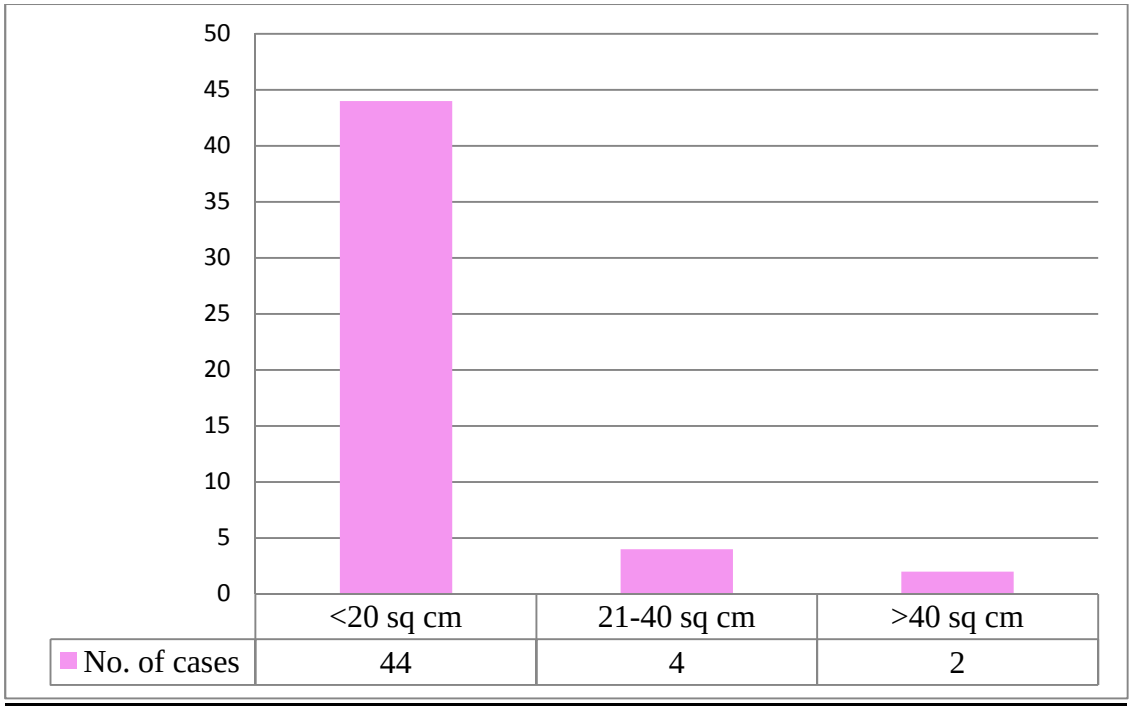
Diabetic and non-diabetic wounds constituted 18(36%) and 32(64%) cases respectively.

TABLE 5: ETIOLOGY - EVALUATION OF WOUND HEALING SCORE ON DAY 7

Location		Day 3		
	N	Mean	SD	Median
Traumatic	20	5.25	0.78	5
Diabetic	16	4.44	1.21	4
Vascular	05	4.80	1.30	5
Total	41	4.88	1.08	5

Kruskal wallis test, p=0.08
Mann-whitney test
Traumatic vs Diabetic – 0.03

CHART 8: WOUND AREA IN SQUARE CM



Wounds of area < 20 sq cm constitute maximum number of cases - 44(88%).

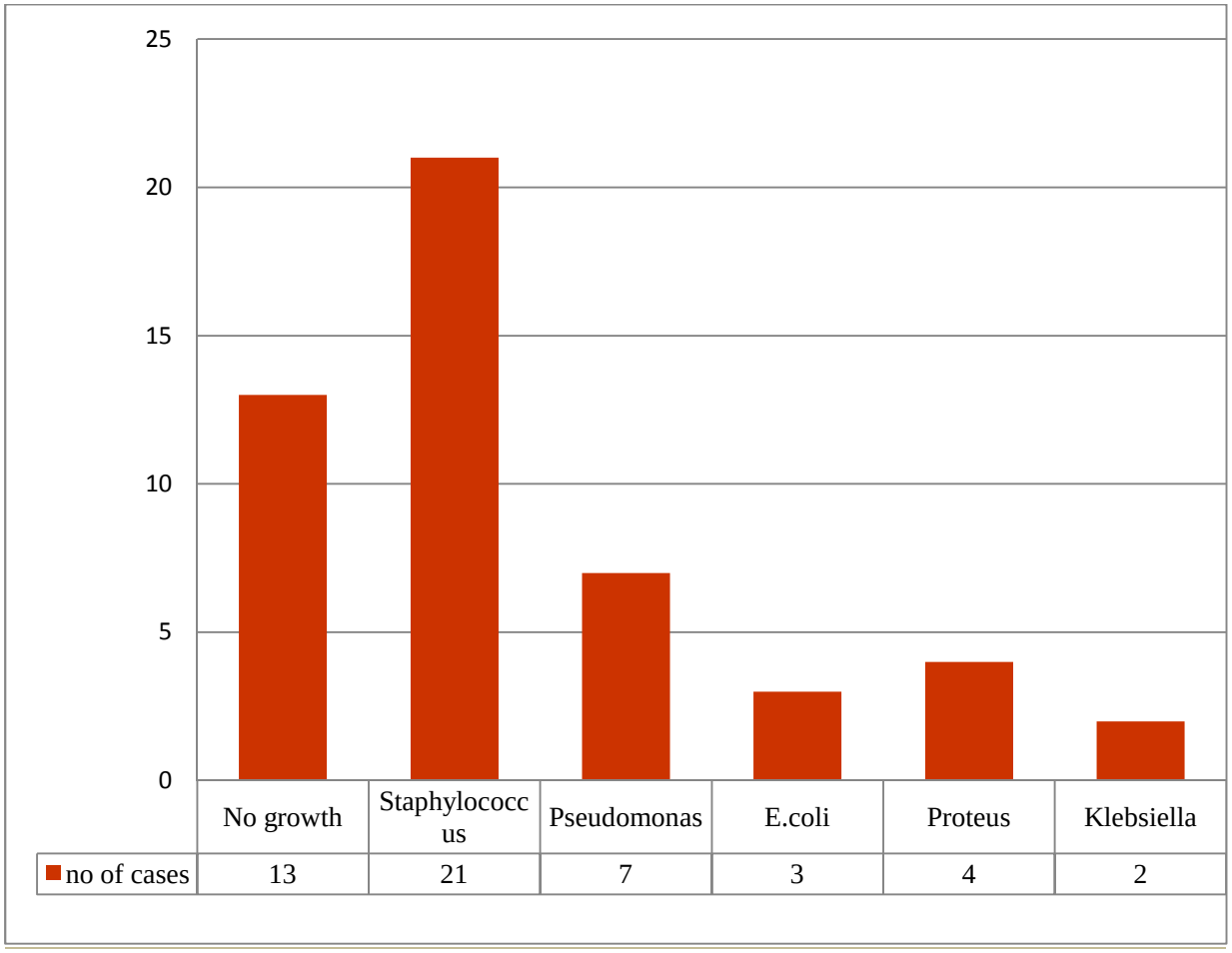
TABLE 6: WOUND AREA - EVALUATION OF WOUND HEALING SCORE ON DAY 7

WOUND AREA	Wound score					
	3.00	4.00	5.00	6.00	7.00	Total
<20 cm^2	**5**	**6**	**15**	**10**	**0**	**36**
21-40 cm^2	**0**	**2**	**0**	**0**	**2**	**4**
>40 cm^2	**0**	**1**	**0**	**0**	**0**	**1**
TOTAL	**5**	**9**	**15**	**10**	**2**	**41**

P value - 0 .001

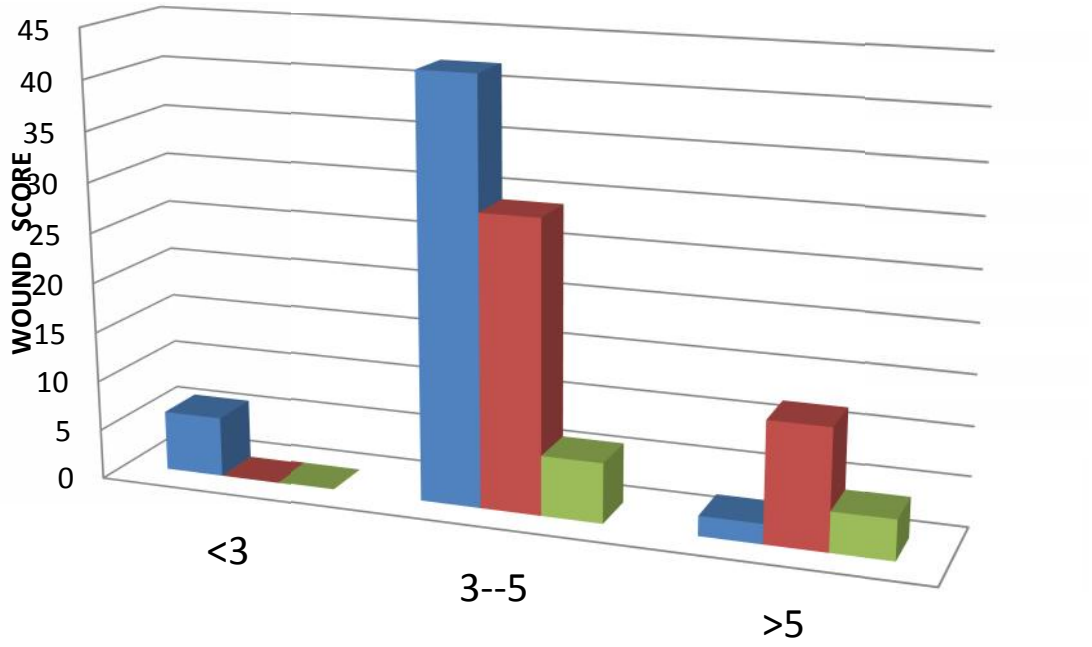
Wound area show an impact on wound healing.
Smaller the wound area,_wound healing was better compared to larger wound area.
P value- 0.001

CHART 9 : ORGANISMS CULTURED FROM WOUND



Most common organism cultured from the wounds was Staphylococcus aureus 21(42%).

CHART 10: WOUND SCORES ON DAYS 3, 7 AND 10

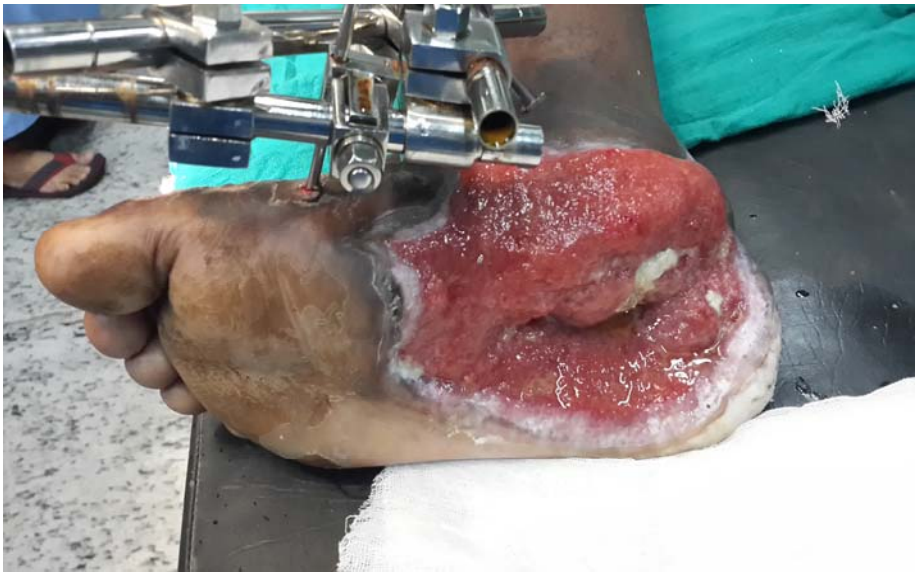


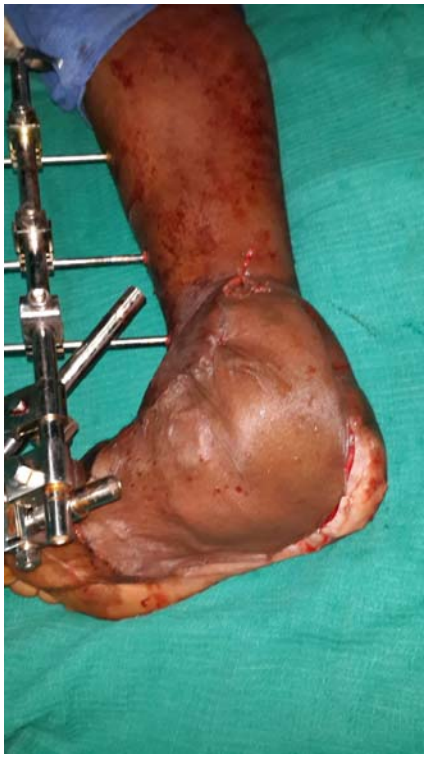
	<3	3--5	>5
DAY3	6	42	2
DAY7	0	29	12
DAY10	0	6	4

Following VAC therapy for 3 to 7 days most of the wounds showed progress in wound healing.

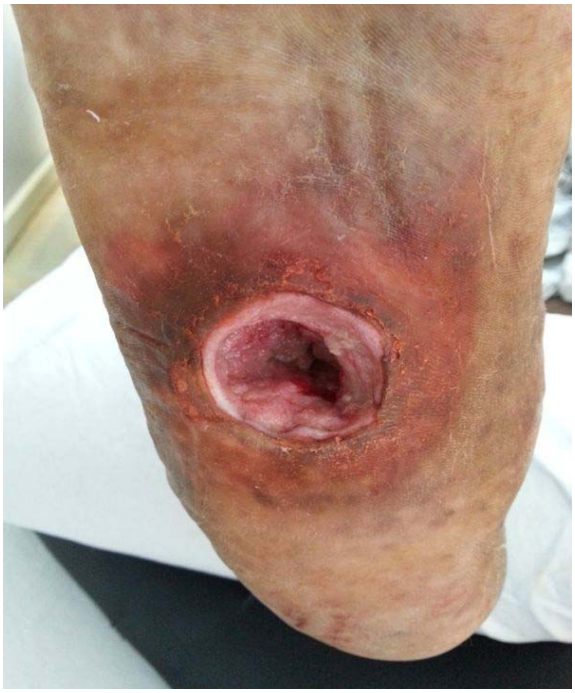
INSTRUMENT

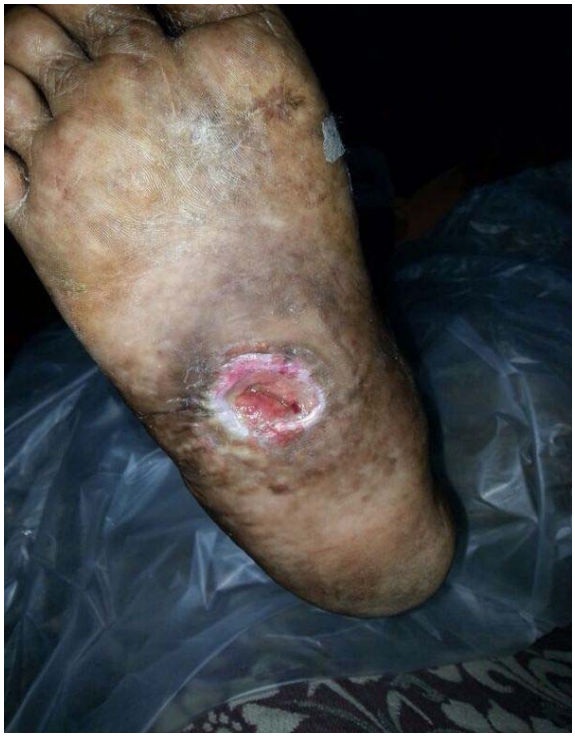
REPRESENTATIVE CASES





REPRESENTATIVE CASES





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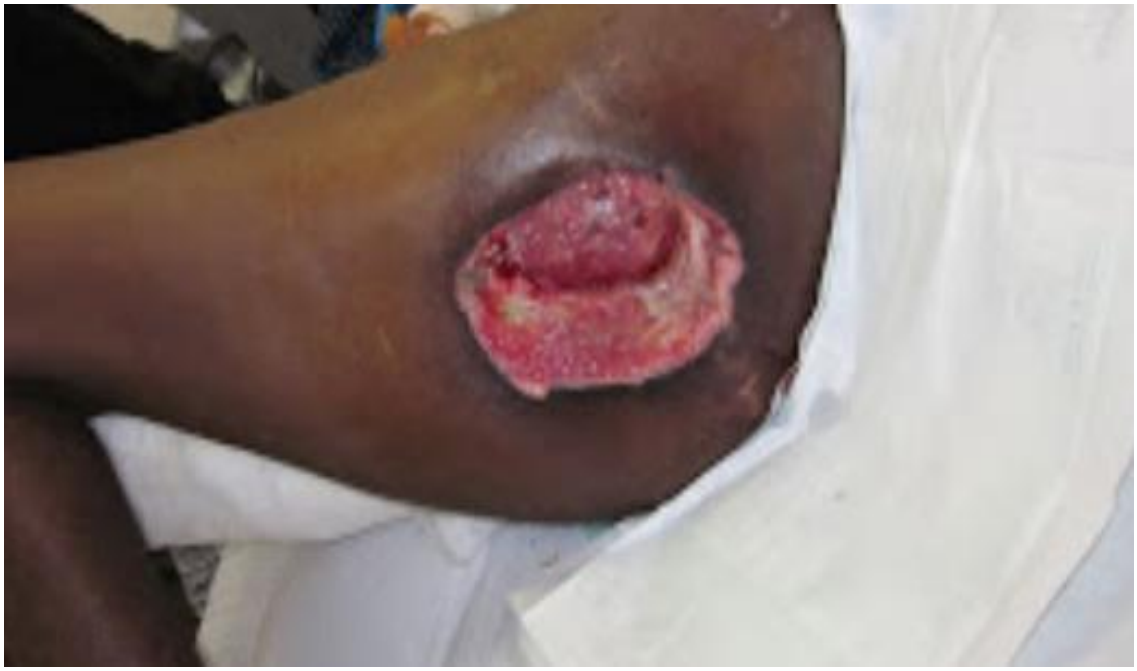

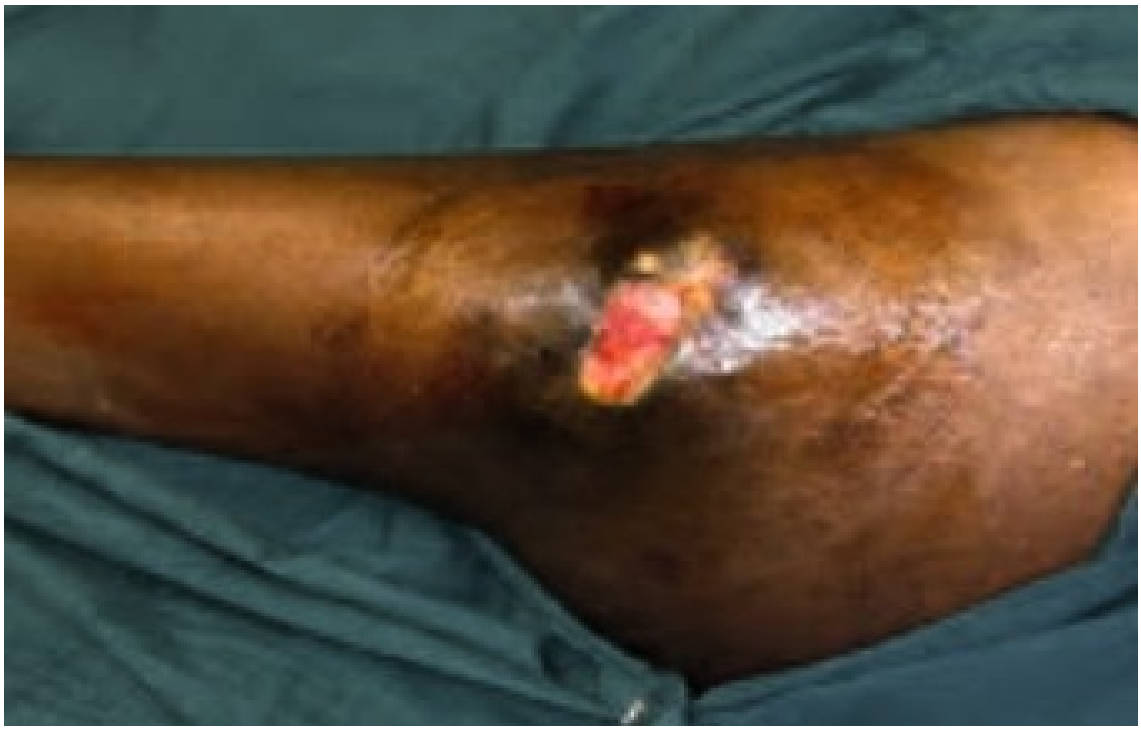

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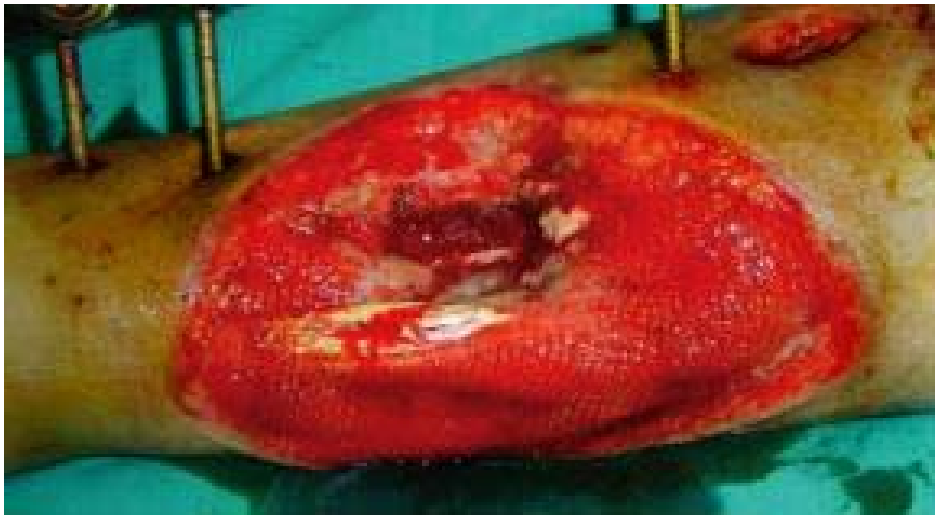

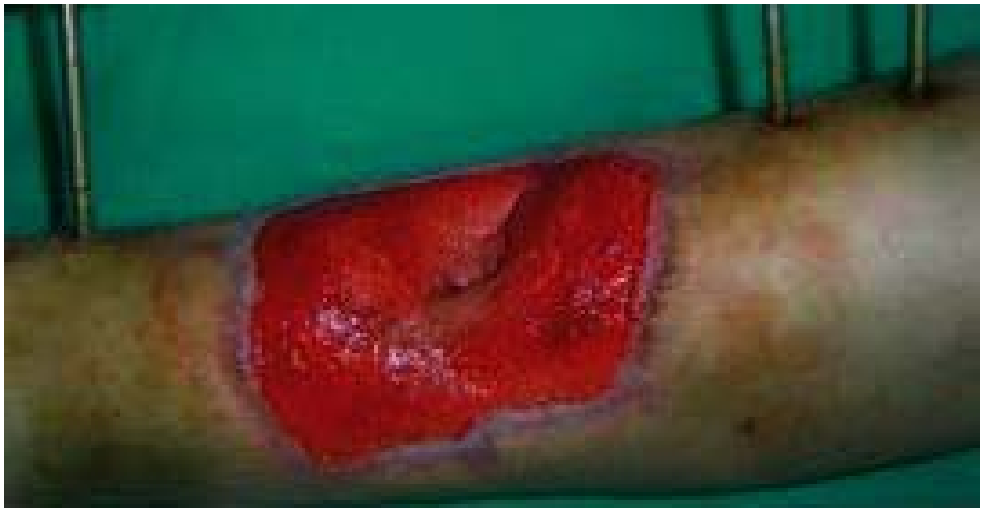

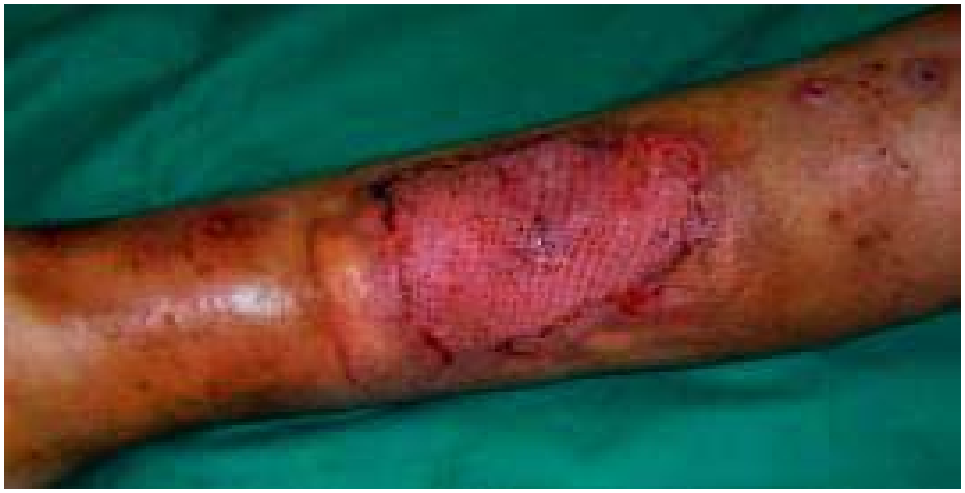

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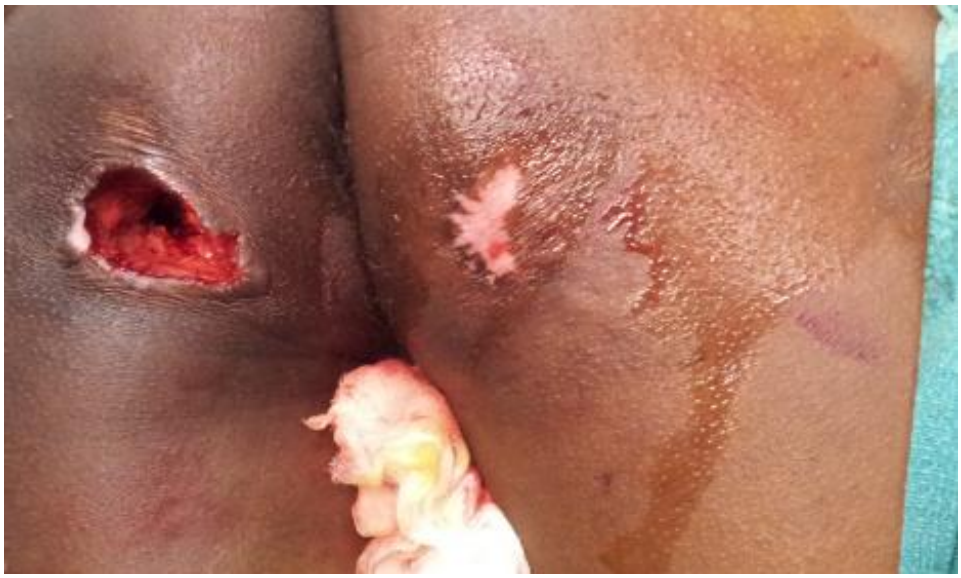

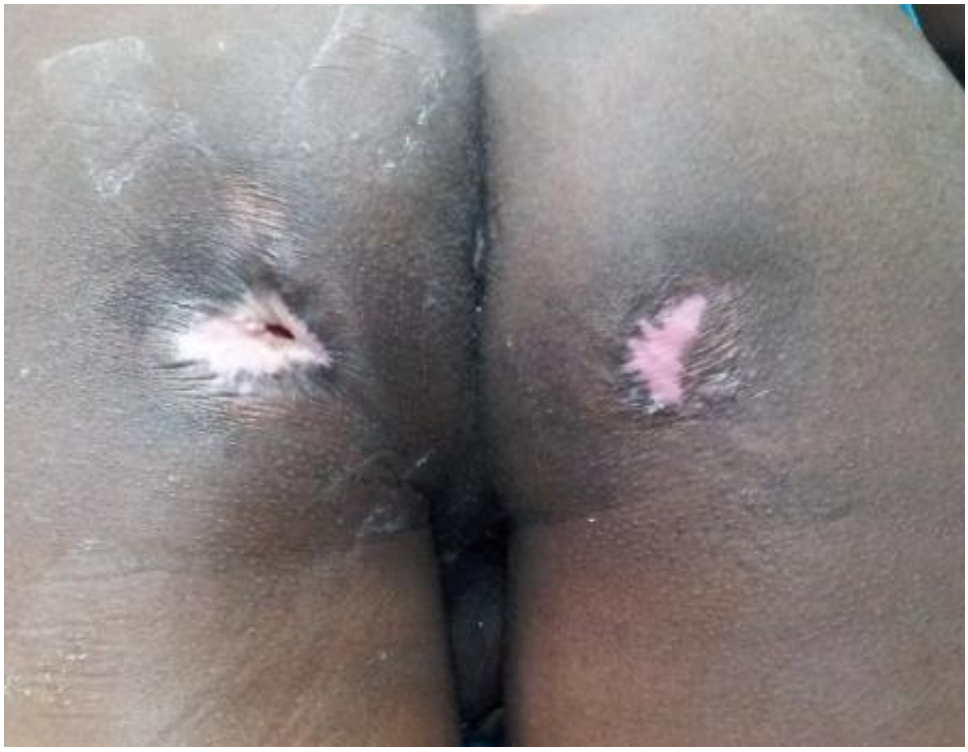

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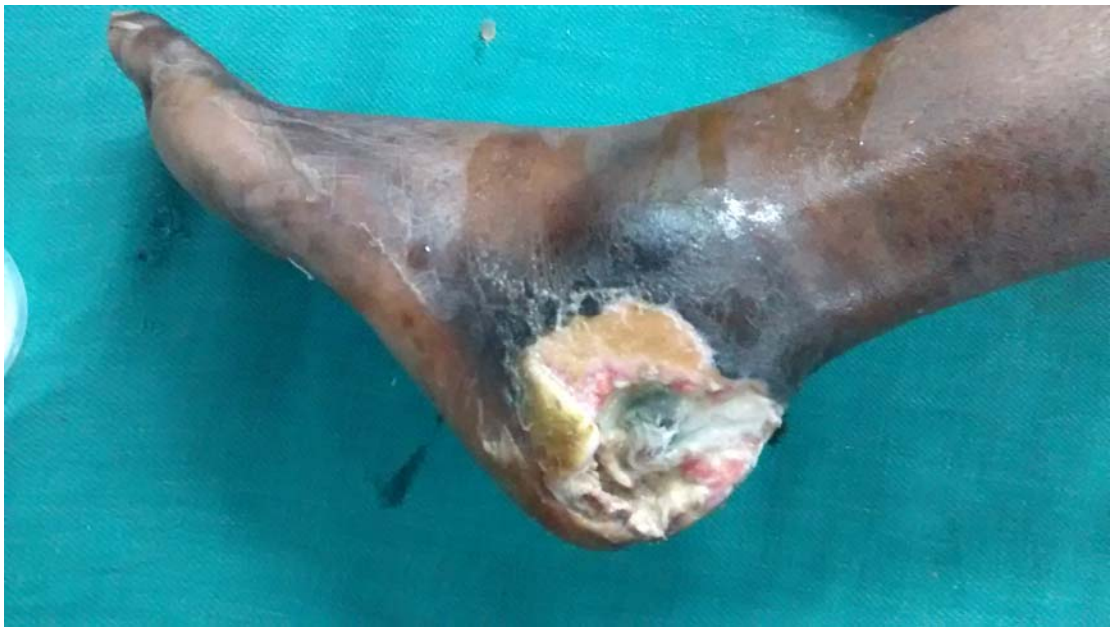

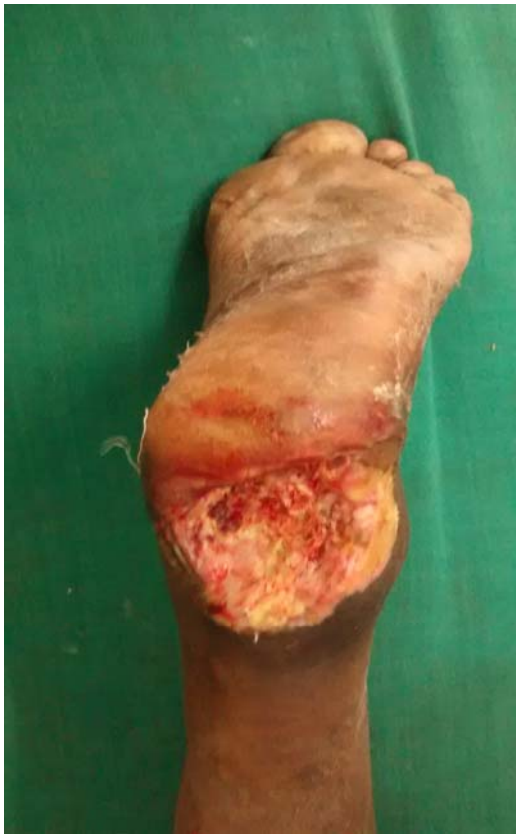

DISCUSSION

Delay in wound healing contributes significantly to the community health problem especially in old adults, This requires frequent visits to the hospital .

With routine wound management, it takes days to months to heal the wound.

Failure of the wound to heal creates a social and financial burden which cause pain and suffering. Vacuum-assisted closure (VAC) therapy is an alternative to the routine wound management, This uses negative pressure to optimise conditions and enhances wound healing and therefor few dressing changes. [32]

Negative pressure therapy is an expensive , a recent report says that usage of VAC as a first-line therapy is not appropriate. However, we say that VAC can be made less expensive by using home brew techniques .

Although clinical results are promising, there is a gap between scientific evidence which is available and usage in clinical practice does not give a balanced view. [33]

Most studies are too small to detect significant differences between those wounds managed by regular dressings and those by VAC,some studies do show VAC to be better in wound healing than standard methods, and with few complications.

VAC is a good alternative for management of complex wounds. VAC is very effective in treating chronic and complex wounds, with a significant decrease in wound size and increase in granulation tissue and duration of treatment . It reduces health care costs and increases patient satisfaction and also the quality of life.

In spite the clinical success of VAC into clinical practice it is not known exactly how it exert effects on the wound. Many mechanisms are suggested . VAC increases local blood flow and decrease the edema fluid and colonization rates of microbes. It promotes wound closure by hastening the formation of granulation tissue as also by the mechanical effects on the wound. It provides a clean moist wound and clears excess wound fluid and creates an ‘‘ideal wound healing environment’’. [34]

In our study, following VAC therapy, wound scoring was done with scores from 1-7 given for area of granulation tissue, color and consistency of granulation tissue. The wounds with scores

> 5 following VAC therapy can be considered for skin graft. In the present study, >70% cases showed wound scores >5 following a week of VAC therapy.

The use of negative pressure dressings, has been shown to be an effective way to accelerate healing of various types of wounds. The optimal pressure for wound healing appears to be minus 125 mm Hg. VAC is usually well tolerated and, has few contraindications or complications, will become a mainstay of wound care.[35]

35.50% of cases among diabetic wounds, and 30% of cases among smokers,showed scores > 5 on day 7 of VAC therapy; thus were showing slower healing in diabetics and smokers in spite of VAC dressings.

Diabetes mellitus compromises wound healing. In a study which examines leukocyte infiltration and presence of tumor necrosis factor-α (TNF) and IL-6 in wounds in normal and induced diabetic mice, there was fewer inflammatory cells in wound fluid taken from diabetic animals (13.8 × 10 6 /ml) when compared to the fluid taken from normal animals (28.5 × 10 6 /ml) on day 7, but there was evidently more IL-6 in fluid from wounds of normal

animals (10,998 U/ml) than in fluid taken from wounds of diabetic animals (2096 U/ml) on Day 7 . there was decreased neo blood vessels and decreased organization of healthy granulation tissue. This tells that delayed healing in diabetes is associated with change in leukocyte infiltration and IL-6 levels in fluid from wounds during the late inflammatory stage of wound healing. [36]

Cigarette smoking and delayed wound healing is well documented and seen in clinical practice . The well known effects of the toxins of cigarette smoke like nicotine, carbon monoxide, and hydrogen cyanide prove that smoking delays and slows wound repair. Nicotine being a vasoconstrictor reduces nutritional blood flow to the skin and results in tissue ischemia and poor healing of wound. Nicotine increases the adhesiveness of platelets and raises the risk of thrombotic occlusion of micovasculature and cause tissue ischemia. Proliferation of RBC's, fibroblasts, and macrophages is decreased by nicotine. Carbon monoxide poisons oxygen transport and also metabolism. hydrogen cyanide has a inhibitory action on the enzyme systems oxydation and prevents oxygen transport at the cellular level. [37]

The increase in the wound complications of surgical patients with diabetes reflects the increase in the incidence of surgical risks and the metabolic abnormalities the disease is associated.

Microvascular disease in diabetes contribute to wound infection and delayed wound healing. [38]

VAC dressings have certainly proven beneficial as a variant method of dressing,

mainly by negative pressure therapy which sucks out serous fluid and help out in formation of granulation tissue. Used in various wounds, continuous suction for a period of 48 hrs andlater intermittent suction depending on wound status have enhanced wound healing process and faster recovery compared to conventional methods of dressing.

Diabetic wounds are always challenging; 18 cases managed by VAC therapy, 7 cases showed improvement in first 3 days of VAC therapy and of the other wounds later did not show improvement on prolonged therapy. Two cases had to undergo amputation as a result of failure of VAC therapy and other conventional methods. The main problem cited with diabetic wounds was infection which flared up in few cases following

closed VAC dressings. Hence diabetic wounds with infections did not benefit from VAC therapy; wound debridement with control of infection, later followed by VAC dressing would be more beneficial.

Non-diabetic wounds; traumatic and vascular benefited from VAC therapy with faster healing in terms of granulation tissue formation. Infection was not a problem in spite of closed VAC dressing.

Traumatic wounds also included cases of iatrogenic wounds. These showed better healing compared to other categories of wounds. There was a case of abdominal wall wound which showed good healing following VAC therapy. There were 7 cases of vascular wounds which included venous ulcers and ulcers associated with peripheral arterial disease. Venous ulcers showed better outcome when VAC was combined with other modalities of management like limb elevation.

Maintaining negative pressure in VAC dressing and the contact of the foam to the wound surface were difficult. These two issues should be taken care of, for more effective usage of the VAC dressing. Other aspects to be considered are wound debridement

and control of infection mainly in diabetic wounds, wherein we can delay VAC therapy until infection is controlled. In spite of the data available, reduction in the bacterial count following VAC therapy practically was more difficult when dealing with diabetic wounds. Finally, even after considering the cost factor for VAC therapy, it is definitely a promising modality of dressing and proven beneficial in different varieties of wounds and enhances wound healing and faster recovery.

CONCLUSION

VAC therapy is a recent modality of treatment of wounds. Its introduction has changed the course of management of wounds. Based on the data from the present study and other studies available, VAC results in better wound healing, with very few complications, and promises to be a good modality in the the management of various wounds. The usage of VAC is simple, but needs minimal training for competent use. Awareness about VAC and training on application of VAC dressings will make it more popular.

SUMMARY

Management of wounds is always a challenging issue. Delayed healing of wounds is a major problem in the community; besides causing morbidity and disability in the patient, is a burden on our health resources. Therefore is a need for application of newer and advanced modalities in management of wounds.

VAC uses negative pressure to enhance wound healing and has a positive impact on wound healing by enhancing granulation tissue formation and wound closure, thus providing a modern wound care system for the poor at an affordable cost.

The present study involved 50 cases of wounds that fulfilled the inclusion criteria.

Patients affected were most commonly in the 5th(36%) decade followed by 6^{th} decade (34%).

There was a male preponderance with male: female ratio of 3.2:1.

Most of the patients in the study presented early with 30(60%) presenting between 10 and 30 days of onset.

VAC dressing was done in wounds in a variety of locations like back and sacrum 20 (40%), leg 16 (32%), foot 5 (10%), ankle and sole 4 (8%) each and abdomen 1 (2%). 27 (54%) of patients were smokers.

Etiology of wounds was determined by history and clinical examination.

Trauma was the most common etiology 25 (50%), followed by diabetes 18 (36%) and vascular causes 7 (14%).

Wound area was recorded before treatment and grouped into <20 sq cm [44cases (88%)], 21-40 sq cm [4cases (8%)] and > 40 sq cm [4cases (8%)].

Staphylococcus aureus was the most common organism cultured 21 (42%) followed by Pseudomonas aeruginosa 7 (14%). No growth was observed in 13 cases.

Wound scores were recorded on days 3, 7 and 10 of VAC therapy. The scoring system used was based on area of granulation tissue, its color and consistency.

There was enhanced granulation tissue formation with faster recovery after application of VAC dressings. Following 3 and

7 days of VAC therapy, wound scores of 5 and above were recorded in 10 (20%) and 27 (54%) cases respectively. Such cases could be considered for skin graft. Out of 18 diabetic wounds , wound scores of 5 and above were observed in 9 cases following VAC therapy. VAC dressing of longer duration are required for diabetic wounds for good outcome.

There was significantly better outcome in non smokers compared to smokers with 75% of non smokers and 58% of smokers showing wound scores >5 on day 7 of VAC therapy.

Thus outcome of VAC therapy depends on various factors like age, aetiology of wounds and existence of co morbid conditions like diabetes and factors like smoking. The candidates for VAC therapy should be chosen after considering these factors with care. From our study, it can be concluded that VAC is a useful in wound healing in various types of wounds. Wherever feasible, VAC therapy should be the modality of choice in management of wounds.

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PROFORMA

CLINICAL EXAMINATION AND INVESTIGATION OF WOUNDS

CASE ID NO: DOA DOD

NAME IP NO AGE/ SEX WARD

ADDRESS

OCCUPATION

Presenting complaints

Wound site Duration

Co morbid conditions

- Diabetes ☐
- Hypertension ☐
- Pulmonary Tuberculosis ☐
- Immuno compromised ☐

H/O Previous hospitalization

Treatment history_____

Personal History ☐
Smoker ☐
Alcoholic ☐

ETIOLOGY

Traumatic ☐ Diabetic ☐ Neuropathic ☐ Venous Others ☐

GENERAL PHYSICAL EXAMINATION

Pallor ☐ Icterus ☐ Clubbing ☐ Lymphadenopathy ☐ Edema ☐ Pulse ☐

BP

ULCER

Site _____

Size _____

Shape _____

Floor _____

Edge _____

Base _____

Surrounding area _____

Regional lymph nodes_____

Neuro vascular deficit_____

WOUND SURFACE AREA

INVESTIGATIONS

Hb%

RBS

CT
BT

BLOOD UREA SERUM CREATININE

URINE: ALBUMIN
SUGAR

MICROSCOPY

PUS – CULTURE AND SENSITIVITY

X-RAY_____

WOUND SCORING SYSTEM

GRANULATION	**SCORE**	**DAY 3**	**DAY 7**	**DAY 10**
NONE	0			
1⁄4 WOUND AREA	1			
1⁄2 WOUND AREA	2			
2/3 RD WOUND AREA	3			
COMPLETE	4			
COLOUR	**SCORE**			
PALE	0			
PINK	1			
BRIGHT RED	2			
CONSISTENCY	**SCORE**			
SPONGY	0			
SOLID	1			

Remarks:

KEY TO MASTER CHART

M : MALE

F : FEMALE

Y : YES

N : NO

D : DIABETICS

T : TRAUMATIC

V : VASCULAR

CASE ID	IP NO	AGE	SEX	DURATION	LOCATION	SMOKING	ETIOLOGY	WOUND AREA	ORGANISM	WOUND SCORE		
										DAY 3	DAY 7	DAY 10
1	56123,	45	M	15	BACK	Y	T	50	STAPHYLOCCOCUS	7		
2	23123, _ _	55	M	30	LEG	Y	V	24	STAPHYLOCCOCUS	4	4	
3	57233,	60	M	15	BACK	Y	D	4	PSEUDOMONAS	3	4	5
4	53128	48	M	60	BACK	N	D	44	PSEUDOMONAS	3	4	6
5	1192	43	M	30	BACK	N	D	22	STAPHYLOCCOCUS	5	7	
6	1321,	33	F	15	ABDOMEN	N	T	24	PROTEUS	4	7	
7	11923,	47	F	15	BACK	N	D	4	E.COLI	4	6	
8	12892,	53	F	10	BACK	N	T	6	STAPHYLOCCOCUS	4	6	
9	2563,	33	M	10	LEG	Y	T	12	STAPHYLOCCOCUS	4	5	
10	35211,	42	M	5	LEG	Y	T	8	STAPHYLOCCOCUS	5	5	
11	23412	57	M	20	BACK	Y	D	18	STAPHYLOCCOCUS	5	6	
12	24512	55	M	15	BACK	Y	D	15	E.COLI	3	3	3
13	24567	45	M	10	BACK	Y	D	12	PSEUDOMONAS	4	3	3
14	23456,	38	M	7	LEG	N	T	15	STAPHYLOCCOCUS	5	6	
15	1357	33	M	10	LEG	N	T	15	STAPHYLOCCOCUS	5	6	
16	1180,	42	M	15	BACK	N	T	2	NO GROWTH	4	4	
17	11952,	46	F	10	LEG	N	T	6	NO GROWTH	4	6	
18	11982,	35	M	7	BACK	Y	V	12	NO GROWTH	5		
19	12900	54	M	9	BACK	Y	V	15	NO GROWTH	5	6	
20	12923	47	F	3	BACK	N	T	4	STAPHYLOCCOCUS	6		
21	53140	39	M	7	FOOT	Y	T	6	STAPHYLOCCOCUS	4	5	5
22	56125/	32	M	3	SOLE	Y	T	4	PSEUDOMONAS	3	5	
23	16234,	41	M	5	LEG	Y	T	8	PSEUDOMONAS	3	5	
24	17110,	53	F	10	LEG	N	D	12	KLEBSIELLA	4	5	7
25	16275	57	M	15	BACK	Y	D	12	PROTEUS	4	5	

26	12165	35	M	20	BACK	Y	D	6	E.COLI	3	4	6
27	13100	46	M	5	ANKLE	Y	V	8	NO GROWTH	3	5	5
28	2592	56	F	7	LEG	Y	D	2	STAPHYLOCCOCUS	4	4	6
29	13121	54	M	10	LEG	N	D	12	PROTEUS	2		
30	2312	44	M	25	ANKLE	Y	V	10	STAPHYLOCCOCUS	3	3	5
31	2411	55	F	30	LEG	Y	D	6	NO GROWTH	4	5	
32	2457	43	F	11	BACK	N	D	12	PSEUDOMONAS	2	4	
33	25561	35	M	12	FOOT	Y	T	9	STAPHYLOCCOCUS	3	5	
34	27804	42	M	14	FOOT	Y	T	4	STAPHYLOCCOCUS	4	5	
35	26775	29	M	14	LEG	N	T	4	NO GROWTH	5		
36	27821	31	M	7	LEG	N	T	6	NO GROWTH	3	5	
37	25142	33	M	7	BACK	N	T	20	STAPHYLOCCOCUS	2		
38	25168	47	F	5	BACK	N	D	6	KLEBSIELLA	4	5	
39	28121	33	F	5	FOOT	Y	T	6	STAPHYLOCCOCUS	3	4	
40	27129	38	M	5	FOOT	Y	T	30	STAPHYLOCCOCUS	2	4	
41	3562	55	M	7	LEG	Y	D	20	PROTEUS	4	3	
42	14523	45	F	15	ANKLE	N	V	2	STAPHYLOCCOCUS	4	6	
43	18912	49	M	15	ANKLE	N	V	2	STAPHYLOCCOCUS	2		
44	19012	56	M	7	LEG	N	T	4	NO GROWTH	4	6	
45	25612	57	M	7	LEG	Y	T	3	NO GROWTH	3	5	
46	26125	60	M	5	BACK	N	T	4	NO GROWTH	4	6	
47	12001	70	M	15	BACK	N	T	4	STAPHYLOCCOCUS	2		
48	28121	59	M	15	SOLE	Y	D	2	NO GROWTH	3		
49	29153	52	M	30	SOLE	Y	T	4	NO GROWTH	4	5	
50	15121	42	M	20	SOLE	N	D	3	PSEUDOMONAS	3	3	

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No : 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. B. Senthil Kumaran,
PG in Plastic Surgery,
Department of Plastic Surgery,
Madras Medical College, Chennai-3.

Dear Dr. B. Senthil Kumaran,

The Institutional Ethics Committee of Madras Medical College, reviewed and discussed your application for approval of the proposal entitled **"The Role of Vacuum Assisted Closure in Complex Wounds"** No.24032014

The following members of Ethics Committee were present in the meeting held on 11.03.2014 conducted at Madras Medical College, Chennai-3.

1.	Dr. C. Rajendran, M.D.	-- Chairperson
2.	Dr. R. Vimala, M.D. Dean, MMC, Ch-3.	-- Deputy Chairperson
3.	Prof. Kalaiselvi, MD Vice-Principal, MMC, Ch-3	-- Member Secretary
4.	Prof. Nandhini, M.D. Inst. of Pharmacology, MMC, Ch-3.	-- Member
5.	Prof. Bhavani Shankar, M.S. Prof & HOD of General Surgery, MMC, Ch-3.	-- Member
6.	Prof. V. Padmavathi, M.D. I/c Director of Pathology, MMC, Ch-3.	-- Member
7.	Thiru. S. Govindasamy, BABL	-- Lawyer
8.	Tmt. Arnold Saulina, MA MSW	-- Social Scientist
9.	Thiru. S. Ramesh Kumar, Administrative Officer, MMC, Ch-3.	-- Layperson

We approve the proposal to be conducted in its presented form.

Sd/Chairman & Other Members

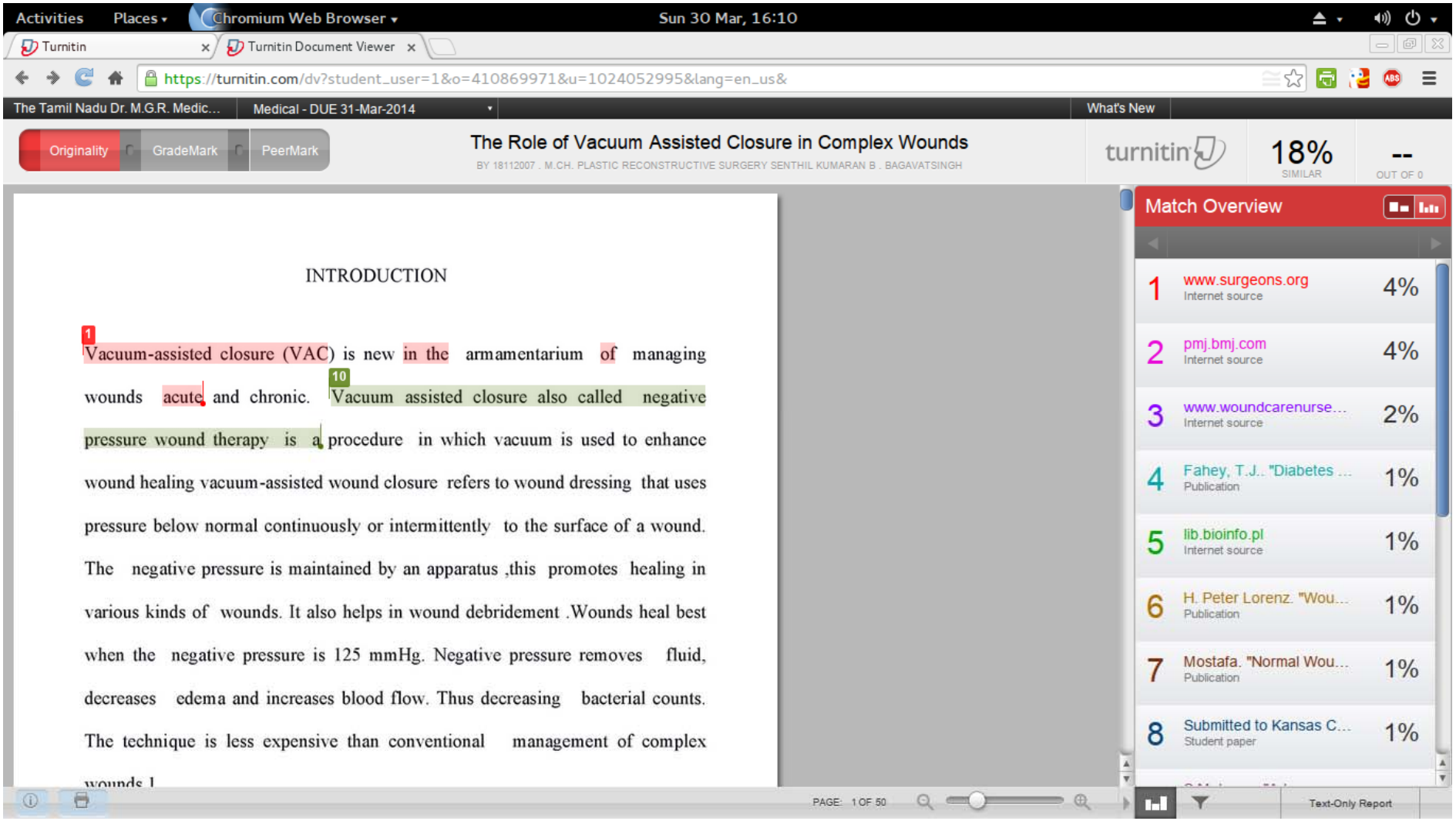
The Institutional Ethics Committee expects to be informed about the progress of the study, and SAE occurring in the course of the study, any changes in the protocol and patients information / informed consent and asks to be provided a copy of the final report.

13/3/14

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

Member Secretary, Ethics Committee

13/3/14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10
Vacuum assisted closure also called negative pressure wound therapy is a procedure in which vacuum is used to enhance wound healing vacuum-assisted wound closure refers to wound dressing that uses pressure below normal continuously or intermittently to the surface of a wound. The negative pressure is maintained by an apparatus ,this promotes healing in various kinds of wounds. It also helps in wound debridement .Wounds heal best when the negative pressure is 125 mmHg. Negative pressure removes fluid, decreases edema and increases blood flow. Thus decreasing bacterial counts. The technique is less expensive than conventional management of complex wounds.1
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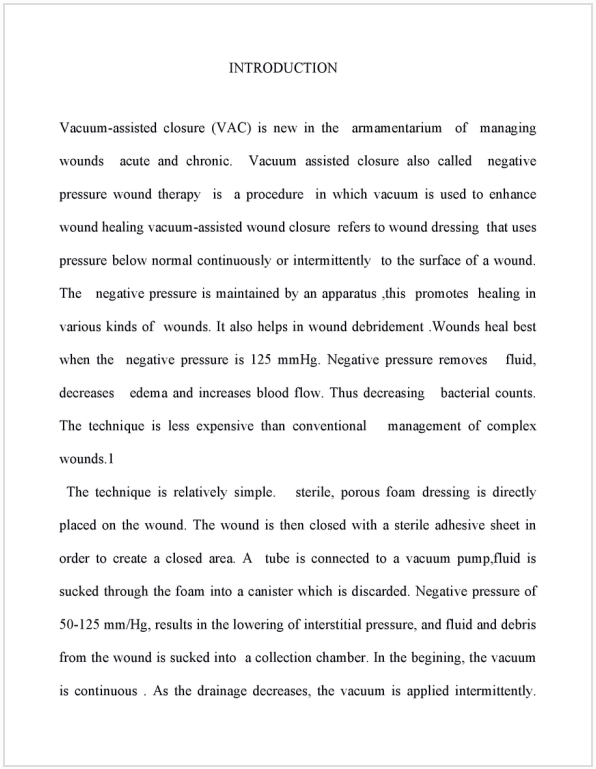

INTRODUCTION

Vacuum-assisted closure (VAC) is new in the armamentarium of managing wounds acute and chronic. Vacuum assisted closure also called negative pressure wound therapy is a procedure in which vacuum is used to enhance wound healing vacuum-assisted wound closure refers to wound dressing that uses pressure below normal continuously or intermittently to the surface of a wound. The negative pressure is maintained by an apparatus ,this promotes healing in various kinds of wounds. It also helps in wound debridement .Wounds heal best when the negative pressure is 125 mmHg. Negative pressure removes fluid, decreases edema and increases blood flow. Thus decreasing bacterial counts. The technique is less expensive than conventional management of complex wounds.1

The technique is relatively simple. sterile, porous foam dressing is directly placed on the wound. The wound is then closed with a sterile adhesive sheet in order to create a closed area. A tube is connected to a vacuum pump,fluid is sucked through the foam into a canister which is discarded. Negative pressure of 50-125 mm/Hg, results in the lowering of interstitial pressure, and fluid and debris from the wound is sucked into a collection chamber. In the begining, the vacuum is continuous . As the drainage decreases, the vacuum is applied intermittently.