A Prospective Randomised Controlled Study To Study The Effect Of Negative-Pressure Dressing On Healing In Wounds Covered With Split-Skin Grafts

A dissertation submitted to the

Tamil Nadu Dr. M.G.R. Medical University,

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M.Ch. Branch III (Plastic Surgery) degree

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CERTIFICATE

I hereby declare that this dissertation entitled **"A Prospective Randomised Controlled Study To Study The Effect Of Negative-Pressure Dressing On Healing In Wounds Covered With Split-Skin Grafts**" is a bonafide research work carried out by Dr.Kiran S Petkar under my guidance in partial fulfillment of requirement for the degree of M.Ch. in Plastic Surgery.

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I hereby declare that this dissertation entitled **"A Prospective Randomised Controlled Study To Study The Effect Of Negative-Pressure Dressing On Healing In Wounds Covered With Split-Skin Grafts**" is a bonafide research work carried out by Dr.Kiran S Petkar under my guidance in the department of plastic surgery in partial fulfillment of requirement for the degree of M.Ch. in Plastic Surgery.

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INTRODUCTION

Split-skin grafting is a technique used extensively in plastic surgery for coverage of wounds as also as a part of various reconstructive procedures. Hence, it takes every available knowledge of the phenomenon of graft take and every possible refinement of the technique to ensure best possible results. The present day conventional techniques of skin grafting are fraught with adversaries of suboptimal graft take due to a less-than-ideal graft bed, difficulty in apposing the graft to the bed, shearing between the graft and the bed and seromas or hematomas under the graft.

Vacuum assisted closure of wounds first described and popularized by Fleischmann in a series of papers in 1990s[1] has ever since been used in the management of wounds in various clinical settings with mixed results[2, 3]. Several animal experiments[4] have recognized that sub-atmospheric pressure increases local blood flow, clears the wound surface of the discharges, reduces bacterial load, decreases edema, increases rate of granulation tissue formation, produces mechanical stress within the tissue resulting in protein and matrix molecular synthesis and enhance epithelialisation.

The technique of vacuum assisted closure (VAC) has also been tried on split-skin grafts and has shown to increase the graft take rates.[5] However, there are few comparative studies between the conventional dressing and vacuum assisted closure on skin grafts which include a wide variety of clinical settings

and measure the graft take as a continuous data. The present study was undertaken to fill this void so as to establish the effect of each method in comparison with one another clinical terms.

AIMS AND OBJECTIVES

Aims and objectives of the study are:

1. To know whether vacuum assisted closure affects the amount of take of a split skin graft.

2. To know whether vacuum assisted closure affects quality of the grafted skin.

REVIEW OF LITERATURE

Skin Grafting

History[6]

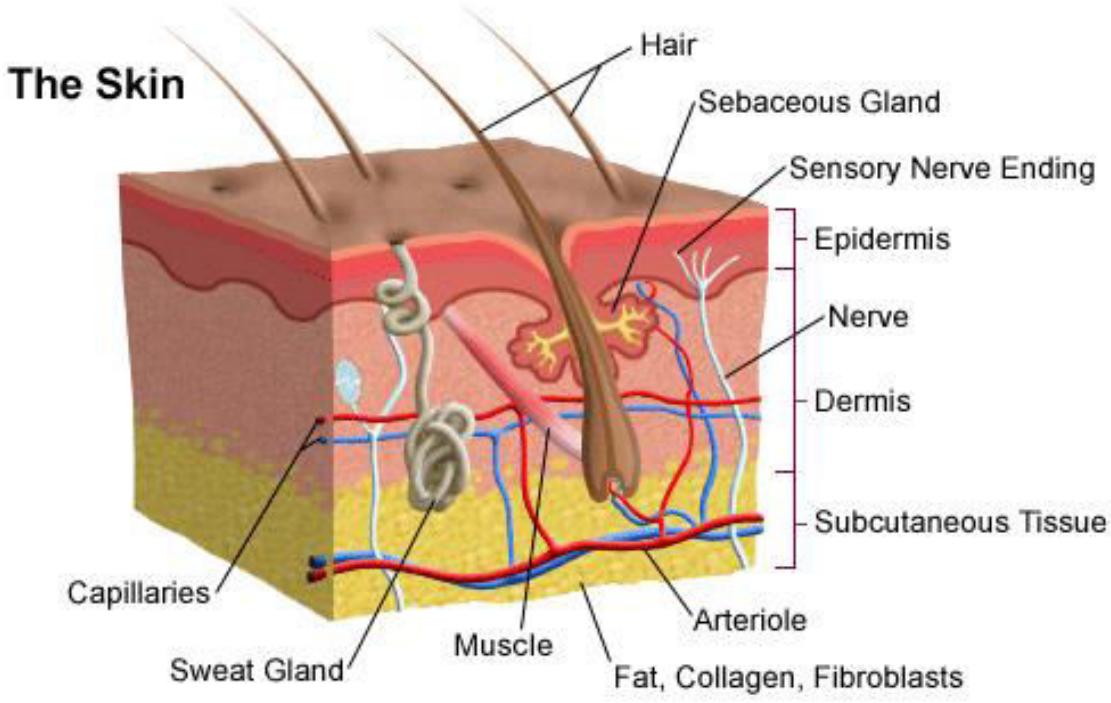
The technique of autotransplantation of skin was born in 1869 in Paris with the successful experimentation by Jacques Reverdin, a medical student from Sweden who placed 2-3mm epidermal grafts on a granulating wound. Later in 1871, George Lawson reported first successful full-thickness skin graft and the subsequent year; Louis Ollier described intermediate-thickness split-skin grafts. Carl Thiersch in 1874 emphasized the importance of graft bed preparation. However, it was not until the description of the technique and its success by V P Blair in 1929 that the technique was well accepted by the surgical community. Blair, along with James Brown differentiated between full-thickness, intermediate-thickness and epidermal grafts and described advantages and disadvantages of each. They explained the technique in detail as also the contraindications and post-operative care.

Thus far, harvesting of skin graft was done free hand using razor or a 25 cm-long blade referred to as Blair knife. Humby, a British plastic surgeon in 1936 developed a knife with a guard to prevent cutting too deep into the skin. In 1939, Earl Padgett with the help of an engineer designed a dermatome with settings for the required graft thickness. In 1940s, the first power-driven dermatome was designed by James Brown.

Skin Anatomy and physiology [6]

The skin is the largest organ of the body. It consists of two distinct layers: epidermis and dermis. Epidermis is avascular and with a process called cornification, it forms a tough layer of dead cells which can withstand the vigors of environment. Dermis on the other hand is the vascular bed to the epidermis.

The skin also contains appendages which include hair follicles, apocrine and eccrine glands and sebaceous glands.



The diagram shows the layers of skin: the epidermis, the dermis, and appendages

Epidermis

The epidermis is the outer layer of skin. The thickness of the epidermis varies in different types of skin. It is the thinnest on the eyelids at .05 mm and the thickest on the palms and soles at 1.5 mm. It contains four types of cells: keratinocytes, melanocytes, Langerhans cells and Merkel cells

The epidermis contains 5 layers. From bottom to top the layers are named:

Stratum basale

Stratum spinosum

Stratum granulosum

Stratum lucidum

Stratum corneum

The process of cornification starts in stratum basale and ends in the formation of the cornified cellular envelope in stratum corneum.

The bottom layer, the stratum basale, has cells that are shaped like columns. In this layer the cells divide and push already formed cells into higher layers. As the cells move into the higher layers, they flatten and eventually die.

The top layer of the epidermis, the stratum corneum, is made of dead, flat skin cells that shed about every 2 weeks.

Specialized Epidermal Cells

There are three types of specialized cells in the epidermis.

The melanocyte produces pigment (melanin)

The Langerhan's cell is the frontline defense of the immune system in the skin[2]

Dermis

The dermis also varies in thickness depending on the location of the skin. It is .3 mm on the eyelid and 3.0 mm on the back.: Dermis is primarily composed of a ground substance with collagen and elastic fibers embedded. It is relatively acellular and contains cells like fibrocytes, mast cells, histiocyes, Langerhans cells, eosinophils, lymphocytes etc.

The dermis is composed of three types of tissue that are present throughout - not in layers. The types of tissue are

Collagen

Elastic tissue

Reticular fibers

Layers of the Dermis

Dermis can be divided into a superficial papillary dermis and a deeper reticular dermis. The former contains a thin arrangement of collagen fibers, is intimately related to the epidermis through lamina densa and nourishes it with its highly developed microcirculation. The reticular dermis on the other hand contains thick bundles of collagen fibers arranged in orthogonal pattern parallel to the surface of the skin with elastic fibers interspersed in between

Specialized Dermal Cells

The dermis contains many specialized cells and structures.

The hair follicles are situated here with the erector pili muscle that attaches to each follicle.[7]

Sebaceous (oil) glands and apocrine (scent) glands are associated with the follicle.

This layer also contains eccrine (sweat) glands, but they are not associated with hair follicles.

Blood vessels and nerves course through this layer. The nerves transmit sensations of pain, itch, and temperature.

There are also specialized nerve cells called Meissner's and Vater-Pacini corpuscles that transmit the sensations of touch and pressure.

Subcutaneous Tissue

The subcutaneous tissue is a layer of fat and connective tissue that houses larger blood vessels and nerves. This layer is important is the regulation of temperature of the skin itself and the body. The size of this layer varies throughout the body and from person to person.

Skin Appendages

Epidermal appendages are intradermal epithelial structures lined with epithelial cells with the potential for division and differentiation. These are important as a source of epithelial cells, which accomplish re-epithelialization should the overlying epidermis be removed or destroyed in situations such as partial thickness burns, abrasions, or split-thickness skin graft harvesting. Epidermal appendages include sebaceous glands, sweat glands, apocrine glands, mammary glands, and hair follicles. They often are found deep within the dermis, and in the face may even lie in the subcutaneous fat beneath the dermis. This accounts for the remarkable ability of the face to re-epithelialize even the deepest cutaneous wounds.

Sebaceous glands.[7]

Sebaceous glands, or holocrine glands, are found over the entire surface of the body except the palms, soles, and dorsum of the feet. They are largest and most concentrated in the face and scalp where they are the sites of origin of acne. The normal function of sebaceous glands is to produce and secrete sebum, a group of complex oils including triglycerides and fatty acid breakdown products,

wax esters, squalene, cholesterol esters, and cholesterol. Sebum lubricates the skin to protect against friction and makes it more impervious to moisture.

Sweat glands

Sweat glands, or eccrine glands, are found over the entire surface of the body except the vermillion border of the lips, external ear canal, the nail beds, labia minora, the glans penis, and the inner aspect of the prepuce. They are most concentrated in the palms and soles and the axillae. Each gland consists of a coiled secretory intradermal portion that connects to the epidermis via a relatively straight distal duct. The normal function of the sweat gland is to produce sweat, which cools the body by evaporation. The thermoregulatory center in the hypothalamus controls sweat gland activity through sympathetic nerve fibers that innervate the sweat glands. Sweat excretion is triggered when core body temperature reaches or exceeds a set point.

Apocrine glands

Apocrine glands are similar in structure but not identical to eccrine glands. They are found in the axillae, in the anogenital region, and, as modified glands, in the external ear canal (ceruminous glands), in the eyelid (Moll's glands), and in the breast (mammary glands).

Hair follicles

Hair follicles are complex structures formed by the epidermis and dermis. They are found over the entire surface of the body except the soles of the feet,

palms, glans penis, clitoris, labia minora, mucocutaneous junction, and portions of the fingers and toes. Sebaceous glands often open into the hair follicle rather than directly onto the skin surface, and the entire complex is termed the pilosebaceous unit.

Blood Supply of the Skin

The cutaneous blood supply comes from the subdermal plexus of vessels. Branches from this plexus supply the skin appendages and end in a plexus located in superficial layer of papillary dermis containing capillary loops. Cutaneous vessels ultimately arise from underlying named source vessels. Each source vessel supplies a 3-dimensional vascular territory from bone to skin termed an angiosome. Adjacent angiosomes have vascular connections via reduced caliber (choke) vessels or similar caliber (true) anastomotic vessels. The cutaneous vessels originate either directly from the source arteries (septocutaneous or fasciocutaneous perforators) or as terminal branches of muscular vessels (musculocutaneous perforators).

During their course to the skin, they travel within or adjacent to the connective tissue framework and supply branches to each tissue with which they come into close contact (bone, muscle, fascia, nerve, fat). They emerge from the deep fascia in the vicinity of the intermuscular or intramuscular septa or near tendons and travel toward the skin, where they form extensive subdermal and dermal plexuses. The dermis contains horizontally arranged superficial and deep plexuses, which are interconnected via communicating vessels oriented

perpendicular to the skin surface. Cutaneous vessels ultimately anastomose with other cutaneous vessels to form a continuous vascular network within the skin.

In addition to the skin's natural heat conductivity and loss of heat from the evaporation of sweat, convection from cutaneous vessels is a vital component of thermoregulation. Cutaneous blood flow is 10-20 times that required for essential oxygenation and metabolism, and large amounts of heat can be exchanged through the regulation of cutaneous blood flow. The thermoregulatory center in the hypothalamus controls vasoconstriction and vasodilatation of cutaneous vessels through the sympathetic nervous system.[7]

Lymphatics

Skin lymphatics parallel the blood supply and function to conserve plasma proteins and scavenge foreign material, antigenic substances, and bacteria. Blind-ended lymphatic capillaries arise within the interstitial spaces of the dermal papillae. These unvalved superficial dermal vessels drain into valved deep dermal and subdermal plexuses. These then coalesce to form larger lymphatic channels, which course through numerous filtering lymph nodes on their way to join the venous circulation near the subclavian vein-internal jugular vein junction bilaterally.[7]

Skin Innervation

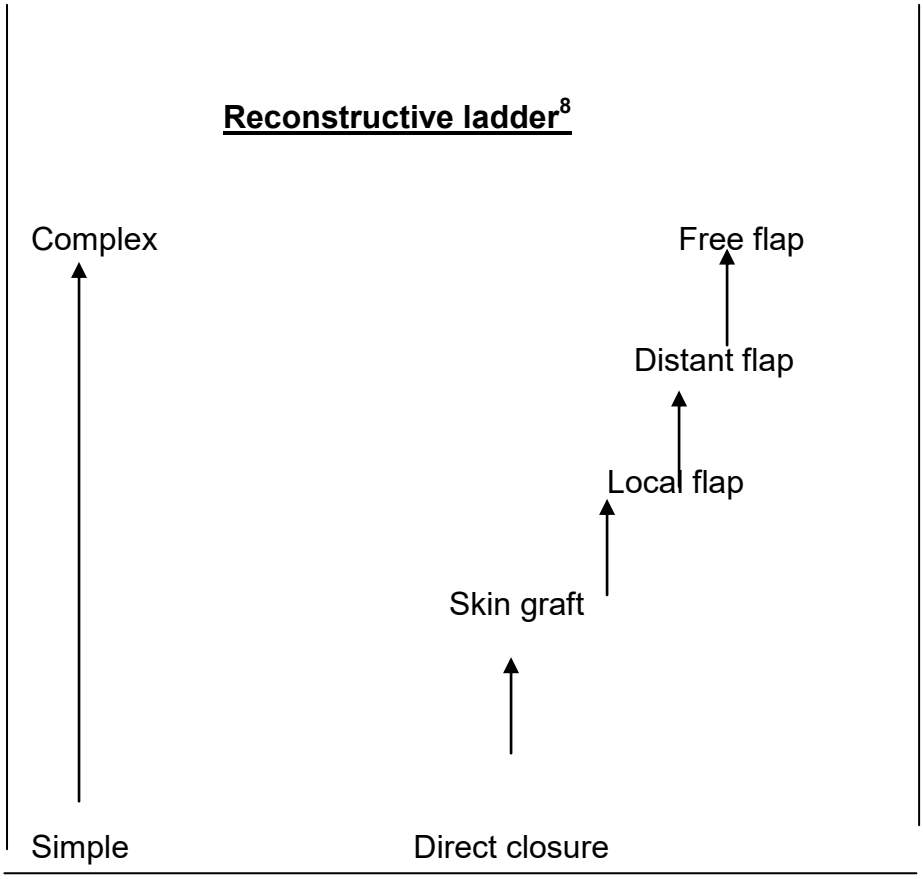
Sensory perception is critically important in the avoidance of pressure, mechanical or traumatic forces, and extremes of temperature. Numerous specialized structures are present in the skin to detect various stimuli. As

previously mentioned, Merkel cells of the epidermis detect light touch. Meissner corpuscles also detect light touch. These are found in the dermal papillae and are most concentrated in the fingertips. Pacini corpuscles are found deep within the dermis or even in the subcutaneous tissue. These structures are specialized to detect pressure.

Pain is transmitted through naked nerve endings located in the basal layer of the epidermis. Krause bulbs detect cold, whereas Raffini corpuscles detect heat. Heat, cold, and proprioception also are located in the superficial dermis. Cutaneous nerves follow the route of blood vessels to the skin. The area supplied by a single spinal nerve, or single segment of the spinal cord, is termed a dermatome. Adjacent dermatomes may overlap considerably, of importance to note when performing field blocks with local anesthesia.[7]

Skin Grafting In Reconstruction

Techniques available to the reconstructive surgeon for the management of surgical defects are considered as a reconstructive ladder progressing from simple to more complex procedure[8]



The role of skin grafting in plastic surgery cannot be overemphasized as it is widely used as a means of reconstruction as also in covering the donor sites of techniques in higher rung of reconstruction ladder.

Skin Grafts

Skin grafts are of two types:

A) Full thickness skin grafts consisting of epidermis and full thickness of dermis

B) Split skin graft consisting of epidermis and a variable proportion of dermis which can be subclassified as:

- Thin split skin grafts
- Intermediate-thickness split skin grafts
- Thick split skin grafts

During its transfer from donor to recipient site, a free skin graft is completely even if only temporarily detached from the body. While so detached, such a graft remains viable for a limited period whose precise limit depends on ambient temperature at which graft is maintained. In order to survive permanently, it has to become reattached and obtain a fresh blood supply from its new habitat. The process which results in its reattachment and revascularization are collectively referred as Take.

The Process of 'Take'[8]

Initially, graft adheres to its new bed by fibrin. Within 48 hours, fibrin starts to break down. During this period, the graft is nourished by the process of plasmatic imbibition into the cut blood capillaries of the graft. This coincides with revascularization by means of outgrowth of capillary buds from the recipient area to unite with those on the deep surface of the graft. This link-up is usually well advanced by third day, recognized clinically by an increase in pinkness in the graft. Adhesion of the graft to its bed is maintained by proliferation of fibroblasts and deposition of collagen to replace the fibrin. The strength of this attachment increases quickly providing an anchorage within four days which allows the graft to be handled safely if reasonable care is taken. More slowly, lymphatic link-up is added and even more slowly, nerve supply is reestablished, although imperfectly and not invariably.

Of these various processes, the ones most relevant in clinical practice are vascularisation and fibrous tissue fixation. The speed with which they are provided and their effectiveness are determined by the characteristics of the bed on which the graft is laid, the characteristics of the graft itself and the conditions under which the graft is applied to the bed.

THE GRAFT BED

The bed on which the graft is laid must be capable of providing the necessary initial fibrin anchorage and also have a rich enough blood supply to vascularise the graft. Muscle and fascia accept graft readily but the ease with which the fat can be grafted varies with the site. On the face, fat is extremely

vascular and grafts take easily; elsewhere, it's relatively poor vascularity makes it a less satisfactory surface to graft. Cartilage which is covered with perichondrium, bone covered with periosteum and tendons covered with paratenon whether parietal or visceral all accept graft readily. Bare cartilage and bare tendons cannot be relied to take a graft, although if the area is small enough, the blood supply of the surrounding tissue may be sufficiently profuse to allow the graft in its vascularisation to bridge the defect and cover it successfully. Bone requires more detailed consideration because its behaviour varies in different sites. Bare cortical bone as typified by outer table of the skull lacks sufficient vascularity to take a graft successfully. In contrast, graft can take on the hard palate and bony orbit. The bone of diploe, exposed when the outer table of the skull has been removed and medullary bone generally will also take graft successfully.

Any surface suitable for grafting on the basis of its vascular characteristics has fibrinogen and enzymes which convert it into fibrin in sufficient quantity to provide the necessary adhesions unless the surface is harbouring organisms which destroy fibrin. The organism par excellence which does this is Streptococcus pyogenes probably by virtue of its potential fibrinolysin. Hence its presence is considered to be an absolute contraindication for skin grafting.

THE GRAFT

Skin grafts can vary both in their thickness and the vascularity of the skin from which they are taken. Variations in graft thickness relate to the thickness of their dermal component and this influences their vascularity, dermis in general being less vascular in its deeper part. In order to get the thickest grafts to take,

conditions have to be little short of ideal. These facts apply to grafts taken from sites other than the head and neck- the abdomen, thigh, arm etc. The head and neck sites commonly used as donor areas have such a rich blood supply that full thickness grafts from one of these sites compare very favorably in their vascular characteristics with thin split skin grafts taken from elsewhere.

CONDITIONS FOR TAKE

Given a bed capable of providing the necessary capillary outgrowth to vascularise a graft and free of pathogens inimical to graft take, the conditions necessary for successful take are close, immobile contact between graft and bed.

Common causes of graft loss include the presence of seroma or hematoma, which separate the graft from its bed and/or shearing movements which prevent adhesion between graft and bed, each in its own way preventing capillary link-up and vascularisation.

Negative-Pressure Dressing

Known in different parts of the world by different names like vacuum therapy, vacuum assisted closure, vacuum sealing or topical negative pressure therapy, this procedure involves the use of vacuum assisted drainage to remove blood or serous fluid from a wound or operation site.

Development of the Negative-Pressure Dressing technique

The practice of exposing a wound to sub-atmospheric pressure for an extended period to promote debridement and healing was first described by

Fleischmann et al in 1993, following the successful use of this technique in 15 patients with open fractures. They reported that the treatment resulted in "efficient cleaning and conditioning of the wound, with marked proliferation of granulation tissue

In two further papers, Fleischmann and colleagues described the treatment of 25 patients with compartment syndromes of the lower limb and 313 patients with acute and chronic infections of various types. Further success with topical negative pressure treatment in Germany was reported by Muller[9] following the treatment of 300 patients with infected wounds, and in 1998 Kovacs et al[10] described how 'vacuum sealing' could be used for the treatment of chronic radiation ulcers, soft tissue injuries including sacral pressure ulcers. Treatment of acute traumatic soft tissue defects and infected soft tissue defects following rigid stabilisation of lower extremity fractures were described by Mullner et al[11.]

In the early studies, negative pressure within the wound was achieved by the use of conventional methods such as wall suction apparatus or surgical vacuum bottles. In 1995, a commercial system for promoting vacuum assisted closure (VAC) was introduced into the United States market. This equipment, called the VAC, was designed

Method of Use-the commercial products[11]

Steps 1-6 demonstrate the technique for vacuum assisted closure:

Step 1

The foam dressing is cut to the approximate size of the wound with scissors (Figure 1) and placed gently into position (Figure 2).

Figure 1 -

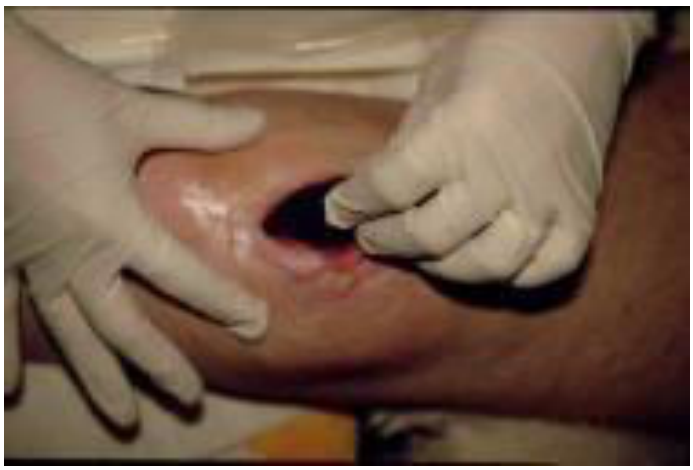


Figure 2 -

Step 2

The perforated drain tube is then located on top of the foam and a second piece of foam placed over the top (Figure 3). For shallower wounds, a single piece of foam may be used and the drainage tube is inserted inside it.

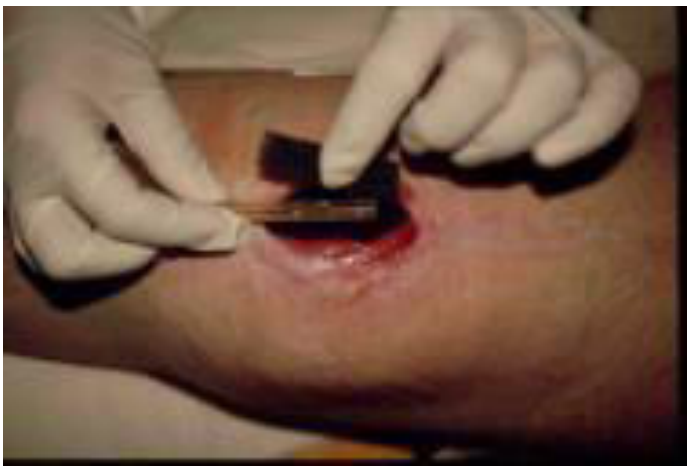


Figure 3 -

Step 3

The foam, together with the first few inches of the drainage tube and the surrounding area of healthy skin, is then covered with the adhesive transparent membrane supplied (Figure 4). At this stage it is important to ensure that the membrane forms a good seal both with the skin and the drainage tube.

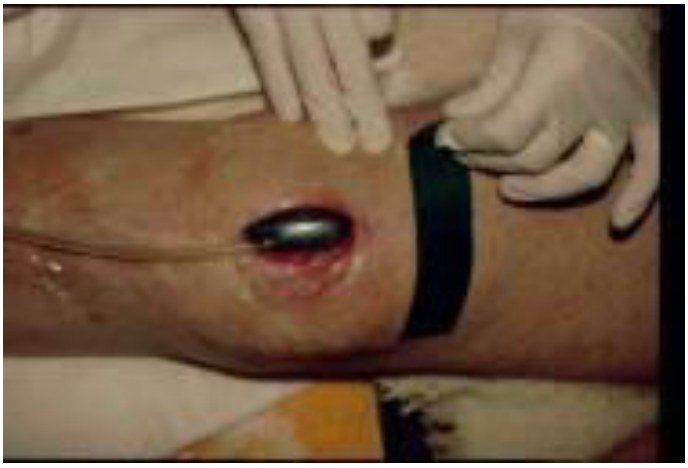


Figure 4 -

Step 4

The distal end of the drain is connected to the VAC unit, (Figure 5) which is programmed to produce the required level of pressure.

Figure 5 -

Step 5

Once the vacuum is switched on, the air is sucked out of the foam causing it to collapse inwards drawing the edges of the wound in with it (Figure 6).

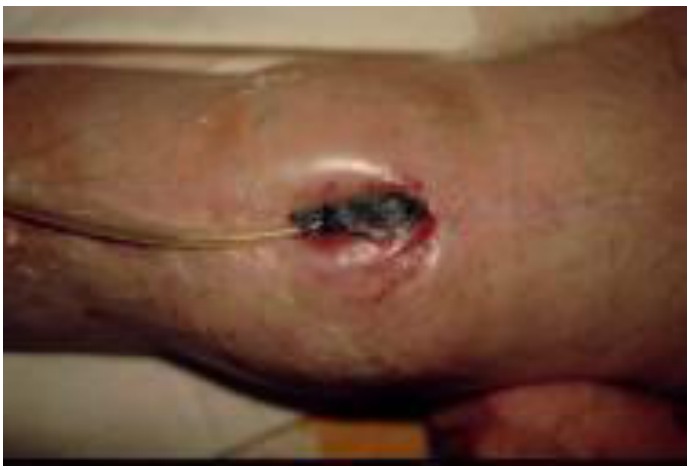


Figure 6 -

Step 6

Fluid within the wound is taken up by the foam and transported into the disposable container within the main vacuum unit.

Negative-Pressure Dressing: Mode Of Action

Morykwas et al[4] conducted animal experiments using negative pressure on Chester pigs. Their findings were:

1. An increase in blood flow equivalent to four times the baseline value occurred with negative pressure values of 125 mmHg, blood flow was

inhibited by the application of negative pressures of 400 mmHg and above.

2. Negative pressure significantly increased rates of granulation tissue formation

3. intermittent or cycled treatment appears more effective than continuous therapy

4. punch biopsy of wounds indicated that, compared with control values, tissue bacterial counts of vacuum-treated wounds decreased significantly after four days.

5. the effect of vacuum therapy was found to increase flap survival by 21% compared with control values

The authors postulated that multiple mechanisms might be responsible for these observed effects. In particular, they suggested that removal of interstitial fluid decreases localised oedema and increases blood flow, which in turn decreases tissue bacterial levels. It has since been proposed that the application of sub-atmospheric pressure produces mechanical deformation or stress within the tissue resulting in protein and matrix molecule synthesis and enhanced angiogenesis .

Fabian et al[13], using the rabbit ear model, provided further hard evidence for the stimulatory effects of sub-atmospheric pressure on the production of granulation tissue and also demonstrated a trend to enhanced epithelialisation. In

experimental partial-thickness burns in pigs, sub-atmospheric pressure was shown to prevent progressive tissue damage in the zone of stasis that surrounds the area of the initial injury. This effect was demonstrable within 12 hours following injury, with treatment times of as little as six hours being sufficient to exert a measurable effect. The authors proposed that removal of oedema fluid containing suspended cellular debris, osmotically active molecules and biochemical mediators, released following the initial injury, may prevent cessation of blood flow.

In their well controlled animal study Fabian et al, investigated the possibility that sub-atmospheric pressure might act synergistically with hyperbaric oxygen (HBO_2). They found, however, that although negative pressure increased the rate of healing compared with control values, HBO_2 therapy did not offer any significant benefit.

Following their animal studies, the same research group (Morykwas and colleagues) described the clinical use of the commercial VAC in 300 wounds of varying aetiology and concluded that VAC is an extremely efficacious modality for treating chronic and difficult to heal wounds[14]. Numerous other papers have described the use of VAC in the treatment of a variety of wound types including extensive degloving injuries[15, 16,], infected sternotomy wounds[17--19], and various soft tissue injuries prior to surgical closure[20.]

With the available studies and reasoning, negative pressure is said to benefit a wound by the following mechanisms:

Negative pressure dressing,

- ☐ increases local blood flow
- ☐ clears the discharges
- ☐ reduces bacterial load
- ☐ decreases edema
- ☐ enhances granulation tissue
- ☐ enhances angiogenesis
- ☐ enhances epithelialisation
- ☐ Protein and matrix molecular synthesis

Over time, the technique of negative pressure dressing has been used in

- ➢ Traumatic wounds
- ➢ Post-surgical wounds
- ➢ Chronic wounds
- ➢ Skin grafts
- ➢ diabetic ulcers

- Pressure sores

- Flaps, etc.

Vacuum assisted closure has also been used in conjunction with split thickness skin grafts and is claimed to be particularly useful for body sites with irregular or deep contours such as the perineum, hand or axilla[21, 22]. Shneider AM et al (1998) used it on more than 100 wounds which included patients of age range 2 months to 97 years. They observed that “No patient has lost a graft because of fluid collecting beneath the skin graft[21]. In all these situations the vacuum helps to hold the graft securely onto the wound bed thus preventing pooling of tissue fluid which would otherwise make the graft unstable.

Molnar et al[23] described how they used VAC in conjunction with skin grafts to treat four patients with full thickness loss of the scalp following a burn injury or excision of an extensive carcinoma. Normally, if such wounds cannot be closed with a flap, the outer surface of the skull is removed to obtain punctate bleeding and a skin graft is applied a week or two later once granulation tissue has started to form. Without this delay the graft take is usually very poor, but with the use of VAC it was possible to apply a successful skin graft immediately after the initial operation.

Moisidis et al[24] conducted a prospective, blinded, randomized, controlled clinical trial and found that although the quantitative graft take was not significant, the qualitative graft take was found to be significantly better with the use of topical negative pressure therapy. They concluded that topical negative pressure

significantly improved the qualitative appearance of split-thickness skin grafts as compared with standard bolster dressing[24].

Llanos S[25], in a randomized, double-masked, controlled trial concluded that the use of NPC significantly diminishes the loss of STSG area, as well as shortens the days of hospital stay. Therefore, it should be routinely used for these kinds of procedures.

The technique nevertheless has its own share of critics. The ardent by far was Ubbink et al[26] who in a systematic review negated the beneficial effects claimed of VAC on wounds due to the lack of randomization and clarity on financial interests in a majority of the studies. A1. Reluctance with regards to VAC also mainly due to the cost of the treatment with commercially available products.

Cost of treatment

The cost of VAC therapy is not insignificant. In addition to the purchase cost or hire charges of the machine itself, it is necessary to purchase disposable foam dressings and drainage tubes, canisters and adhesive drapes, which together could easily cost in excess of $50 (Rs 2000) per day (ref: www.kci1.com). However, with some modifications utilizing the locally available materials, the cost can be significantly and practically reduces as was demonstrated in the present study.

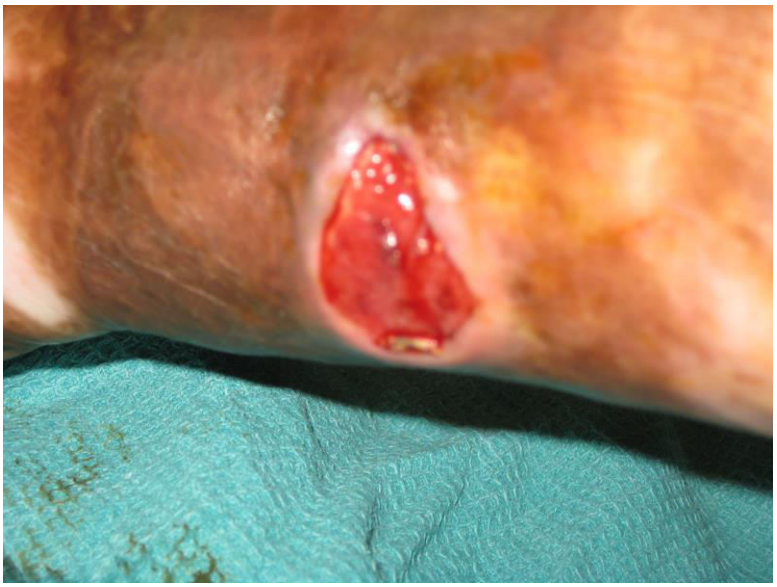
MATERIALS AND METHODS

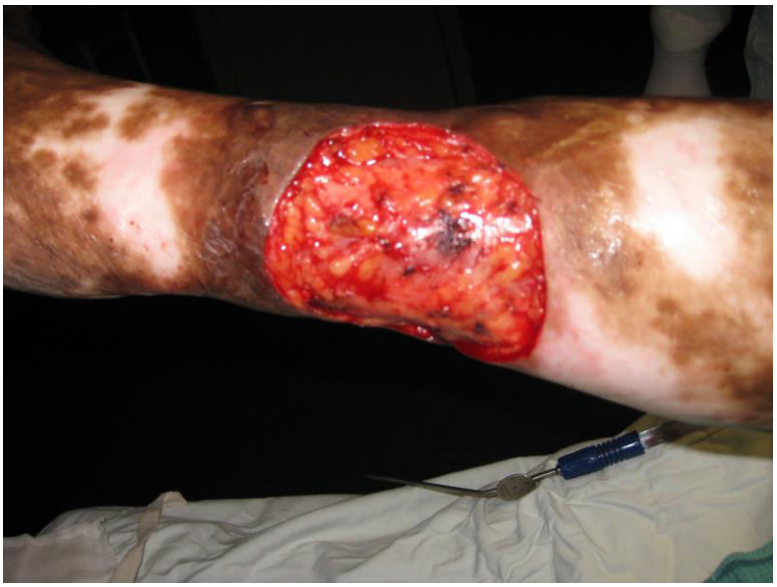
The study was conducted at Christian Medical College Vellore. Ethical clearance was obtained from the Institutional Review Board. Consecutive patients undergoing split-skin grafting for any reasons who were consenting for the study were enrolled excluding those with known bleeding tendencies. The patient characteristics, the nature of wound, its size and the tissue at the floor of the ulcer at the time of skin-grafting were noted. Patients were randomized into study and control groups using an open list of computer-generated random numbers.

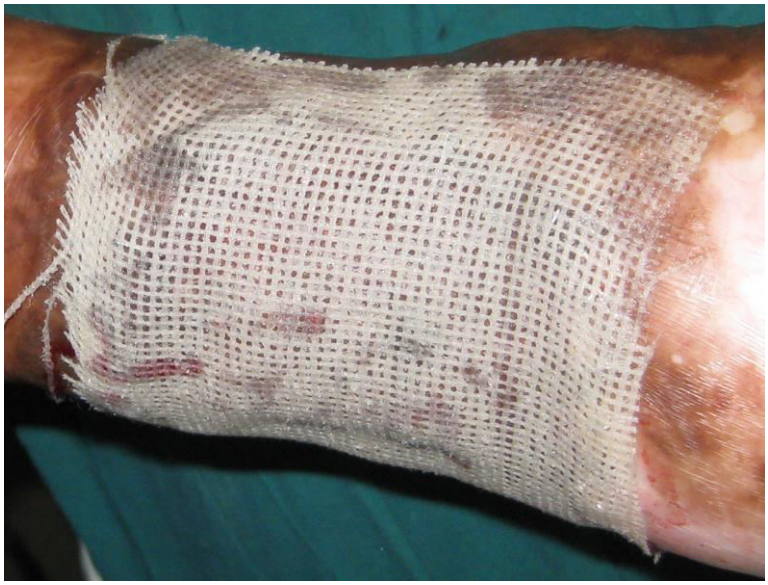
After the split-skin graft was laid and secured as necessary, the control group received a dressing consisting of a Vaseline gauze, cotton pads and cotton bandage (for limbs) or elastic adhesive bandage (for trunk) in that order from deep to superficial. In the study group, vaseline gauze was placed on the graft, on which a low-density polyurethane foam of one and half inch thickness cut to the shape of the graft was placed. A flexible transparent plastic tube of 5mm inner diameter and 1meter length was perforated at sides near one end and the same was inserted into the foam by making a shallow slit in the latter.

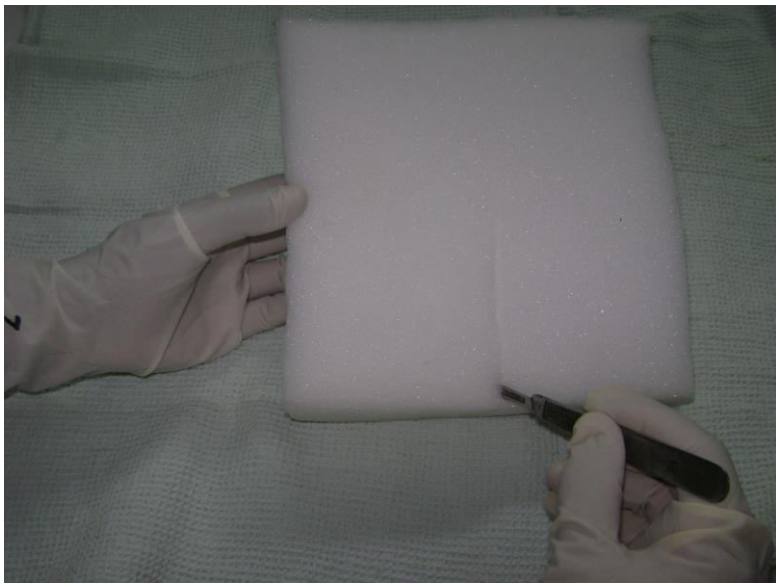
The whole assembly was covered by a broader transparent adhesive film (opsite) whose edges were sealed to the normal skin surrounding the dressing so that the dressing is isolated from the environment except through the lumen of the plastic tube. The tube was then connected to a continuous wall suction of 80 mm Hg when the patient was shifted from the operation theatre. Effective creation of negative pressure was confirmed by watching for the collapse of the

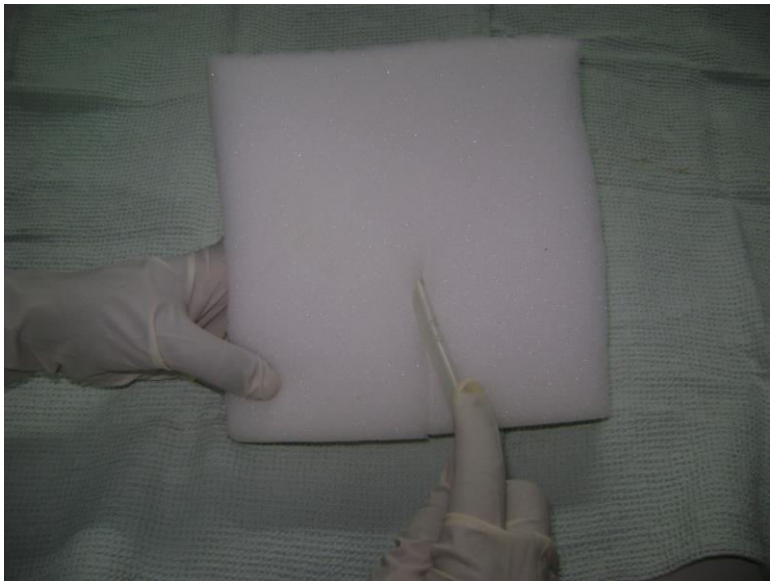
foam and absence of gushing sound of air leak into the system. Splinting and/or elevation of the grafted part was done when deemed necessary in both study and control groups.

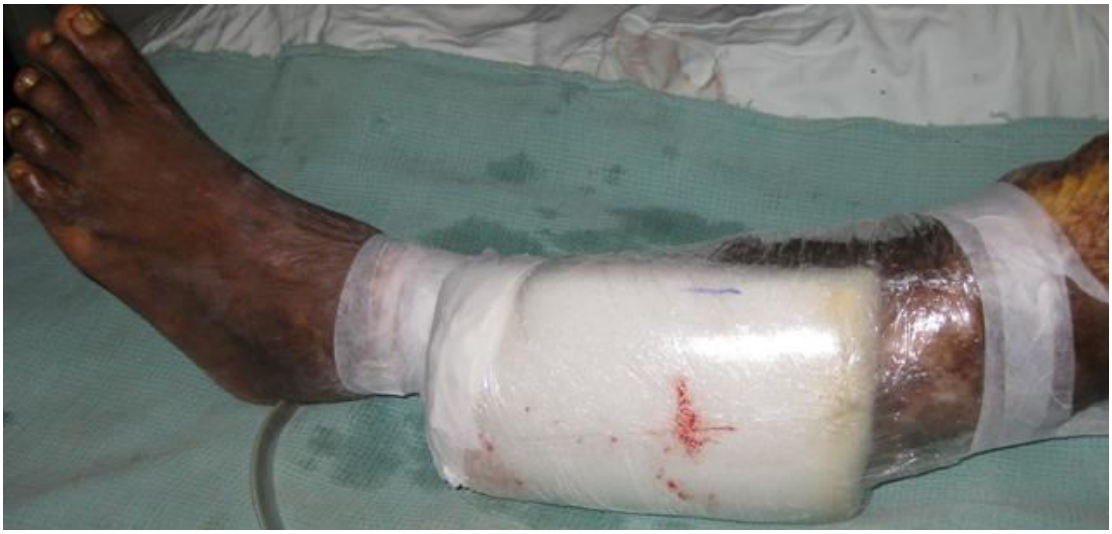


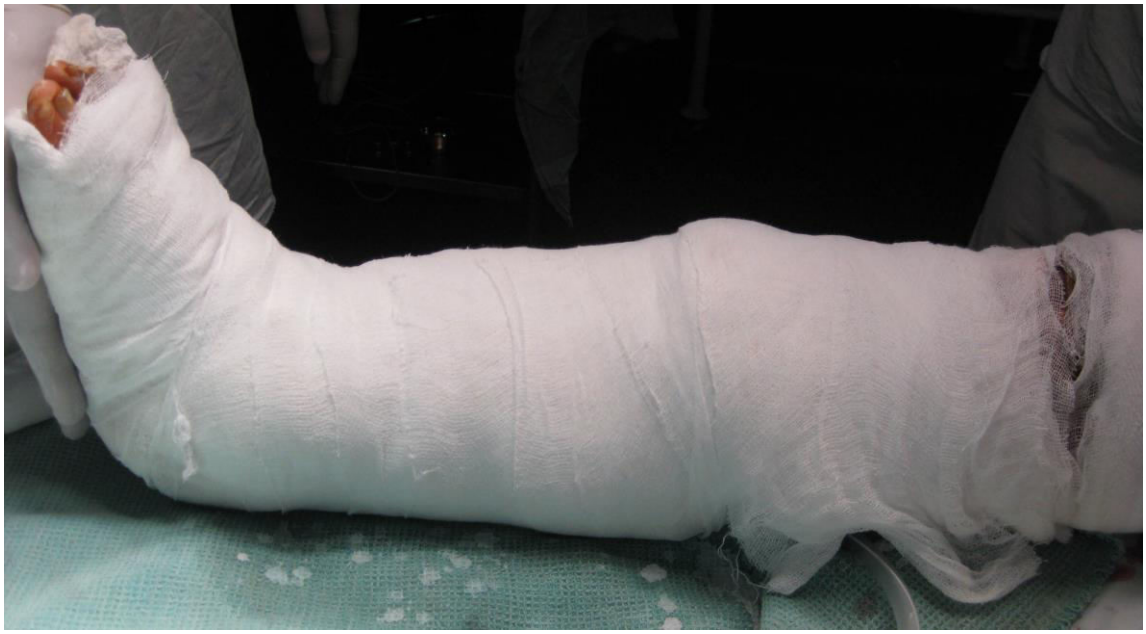


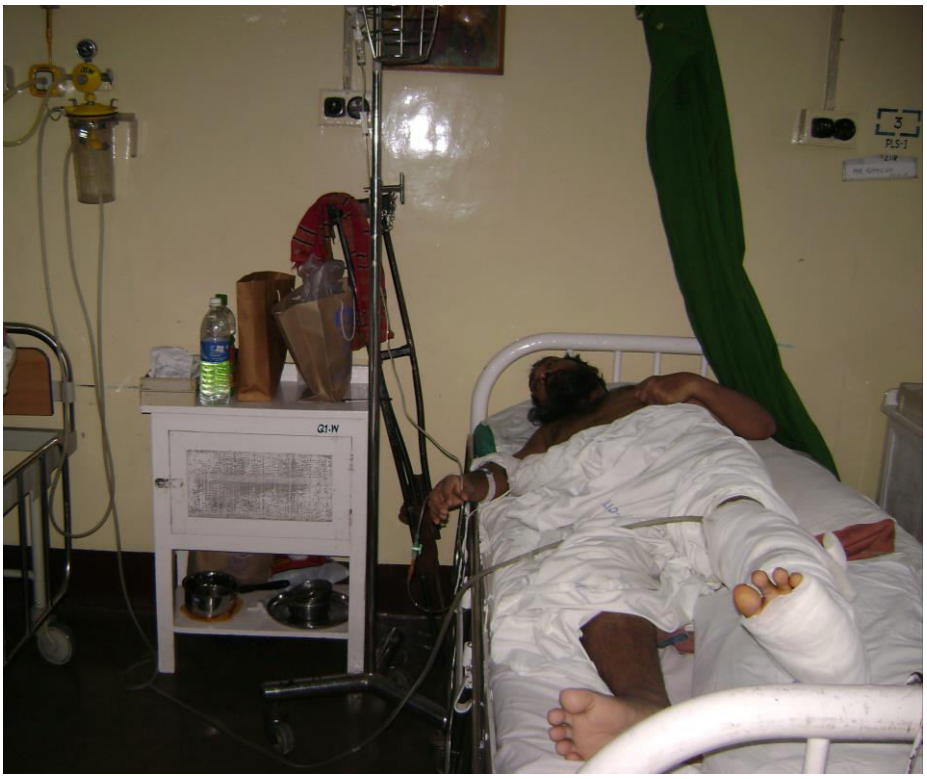












The grafts were inspected on fourth post-operative day after which, negative pressure if used was discontinued. The patients were followed up for a total of three weeks to note the speed and quantity of graft take, quality of the graft and overall healing of the grafted area. Patient and ulcer characteristics were cross tabulated and independent t-tests were applied to the outcomes to find out the statistical significance.

RESULTS

A total of 72 split skin grafts were put on 64 patients. Forty three of them were males and twenty nine were females. Half the patients were cases and half were controls. Mean age of the patients in controls was 34.31 (range: 16-77) years and in cases was 35.69 (Range: 2-69) years. Indications for skin grafting (table 1), tissue at the graft bed at the time of grafting (table 2) and median size of the grafted area (table 3) were comparable between the two groups.

NATURE OF WOUND

		use of NPD		Total
		no	**yes**	
nature of wound	fresh surgical wound	17	9	26
	acute wound	1	3	4
	Traumatic wound	4	9	13
	Burn wound	8	7	15
	Diabetic wound	0	4	4
	post-inflammatory wound	6	4	10
Total		36	36	72

Table 1

GRAFT BED

		use of NPD		Total
		no	**yes**	
ulcer bed	Granulation tissue	18	23	41
	Fascia	3	1	4
	Muscle	2	2	4
	connective tissue	12	8	20
	Healicoll	1	2	3
Total		36	36	72

Table 2

Ulcer size

	N	Minimum	Maximum	Mean	Std. Deviation
Controls	36	9	1200	269.06	336.743
Cases	36	9	1000	235.33	296.386

Table 3

The additional cost of the VAC assembly for an average sized ulcer was Rs 450. The vacuum closure assembly was well tolerated by all patients including children as young as two years. Patients were not any more inconvenienced than they were with the routine bed rest and immobilization. No serious adverse effects were noted in either group.

Final graft take at two weeks in the study group ranged from 0-100 per cent with an average of 92.22 per cent graft take (SD:2.83) while the control group showed a graft take ranging between 0-100 percent with an average graft take of 86.17 percent (SD:4.23) (fig 4). Two wounds treated with NPD and 5 wounds treated with conventional dressing required a second surgery due to partial or complete graft loss.

Graft take in percentage

	use of NPD	N	Mean	Std. Deviation	Std. Error Mean
graft take-D9	no	36	87.47	23.596	3.933
	yes	36	93.64	16.498	2.750
D14	no	36	86.17	25.370	4.228
	yes	36	92.22	16.993	2.832

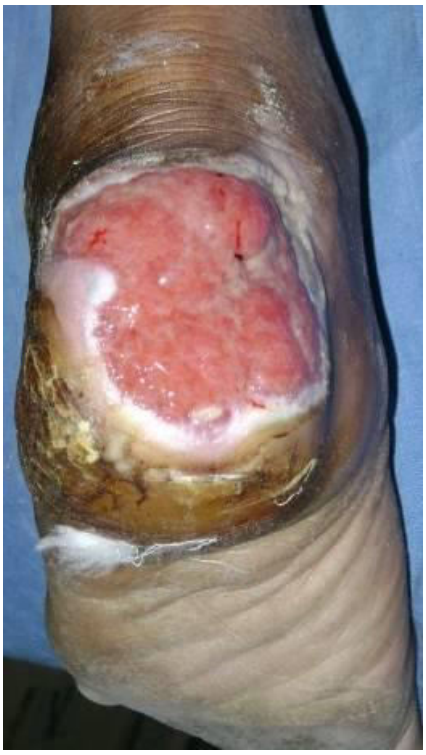
Table 4

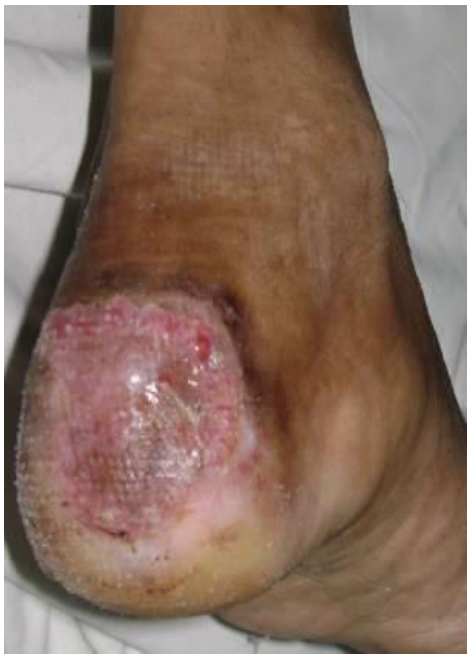
The quality of the graft was average in majority of patients in either group. However, in those with above average graft quality, 84.8% were cases and 15.4% were controls (table 5)

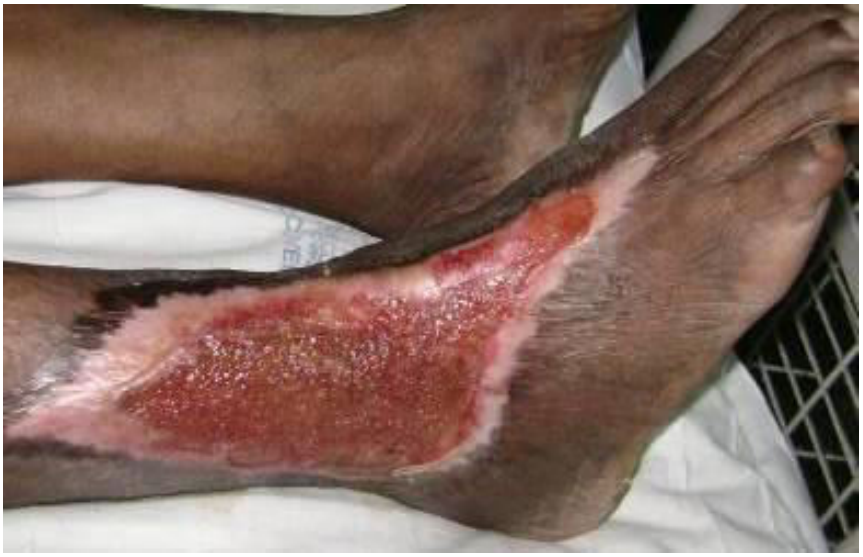
Quality of graft

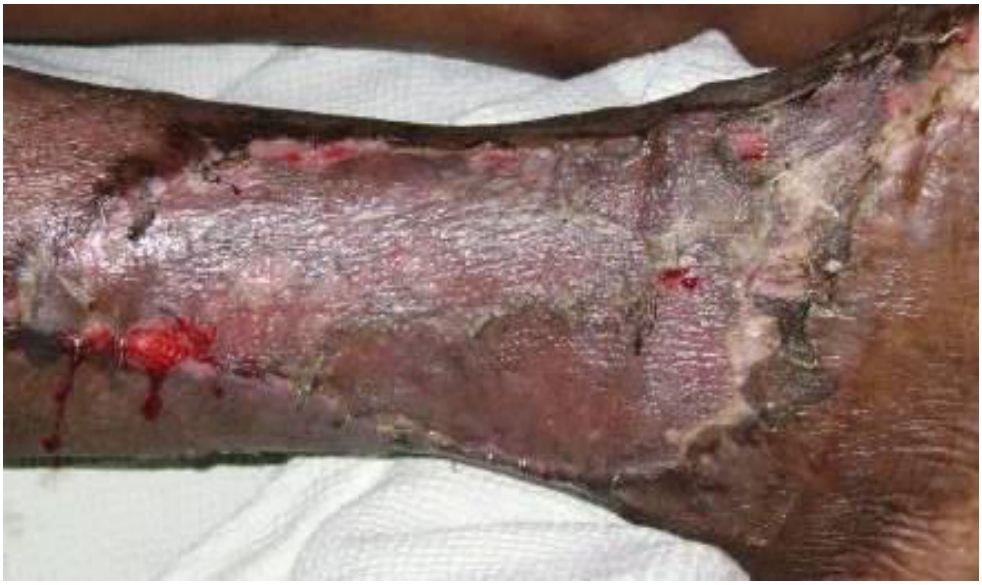
			use of NPD		Total
			no	yes	
quality of graft	above average	Count	2	11	13
		% within quality of graft	15.4%	84.6%	100.0%
	average	Count	31	24	55
		% within quality of graft	56.4%	43.6%	100.0%
	poor	Count	3	1	4
		% within quality of graft	75.0%	25.0%	100.0%
Total		Count	36	36	72
		% within quality of graft	50.0%	50.0%	100.0%

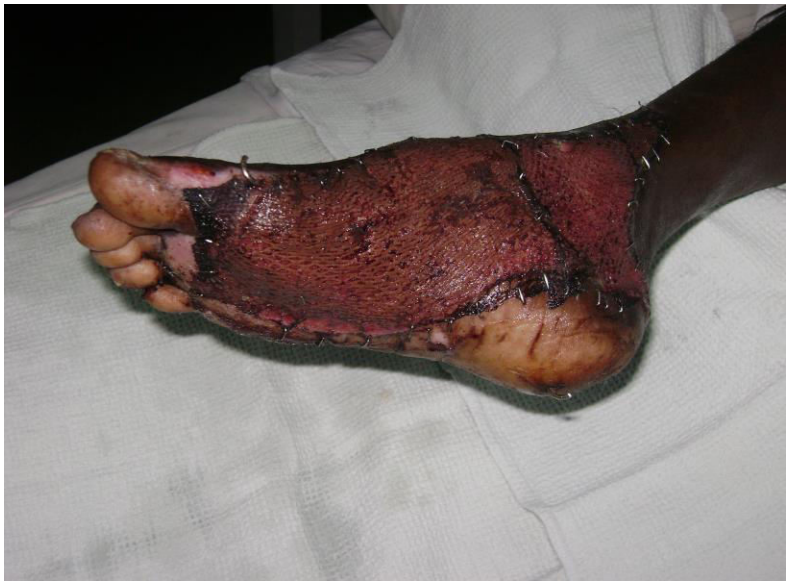
Table 5

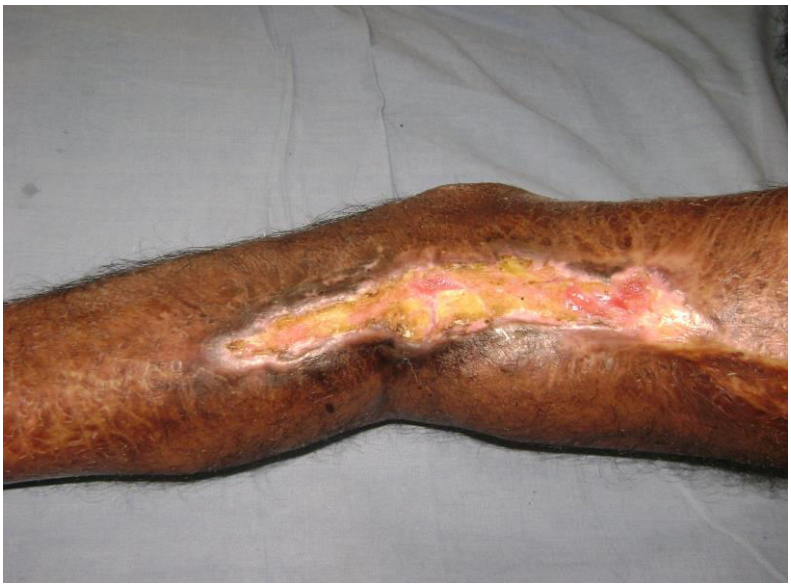


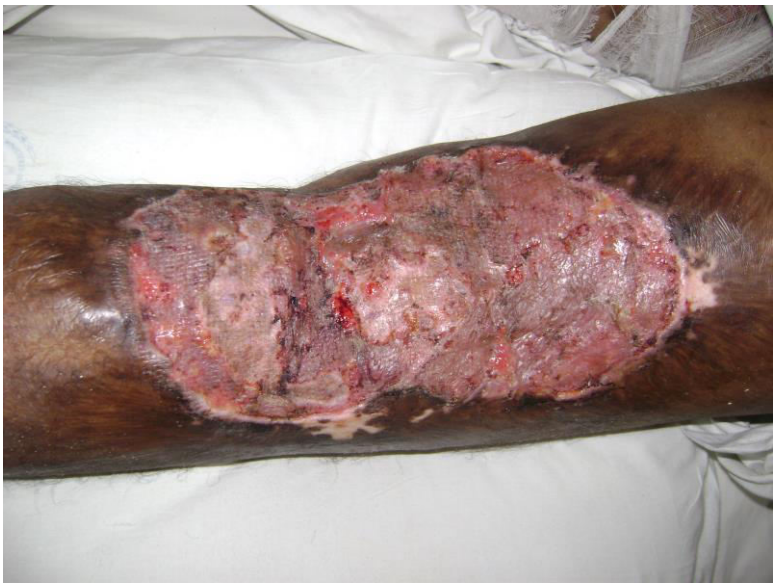


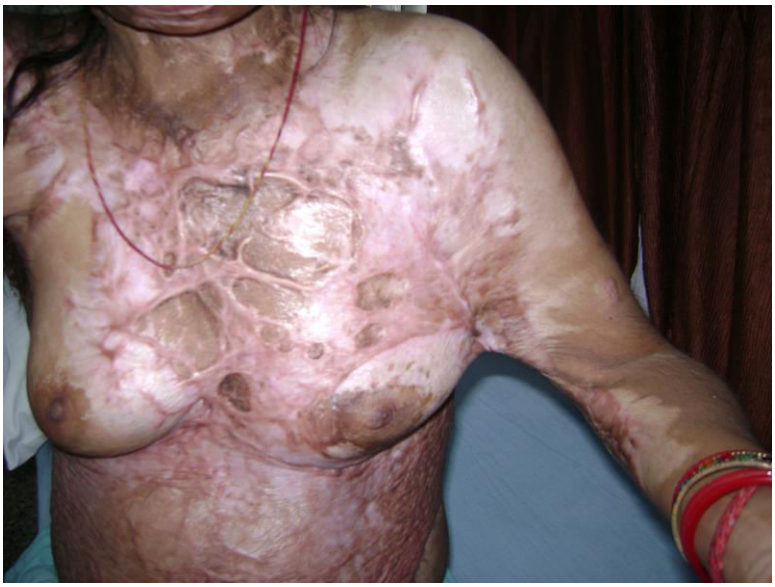


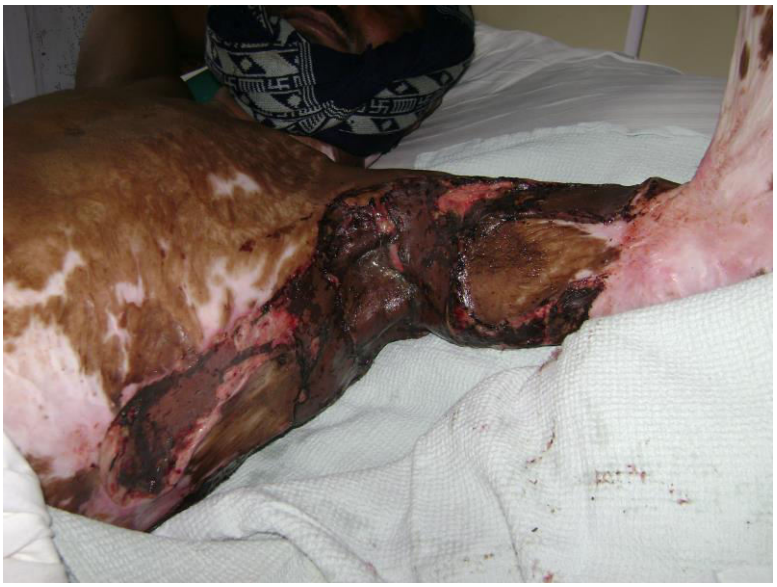


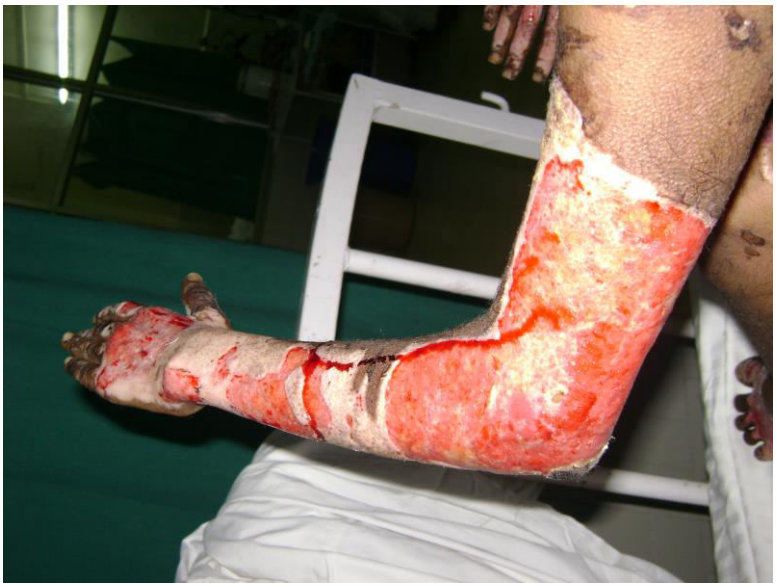


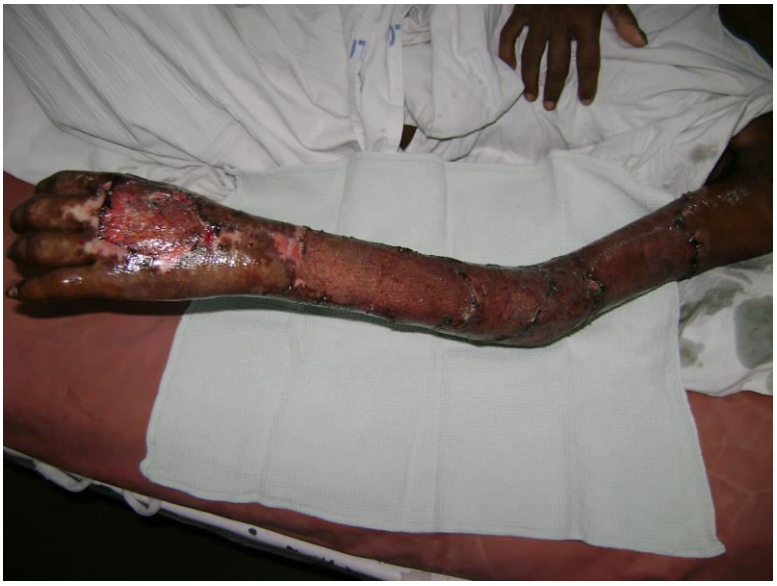












DISCUSSION

Split-skin grafting is an operative procedure whose usefulness in plastic surgery cannot be overemphasized. However, the technique often fails to give satisfactory results particularly when the three important aspects, namely the graft, the graft bed and the grafting conditions are anything less than ideal. Although one cannot deny the all importance of patient selection, preparation of wound and meticulous execution of the procedure to achieve good or fair results, a technique of skin grafting that can give consistently good results in terms of take and quality of the grafted skin is the Holy Grail in plastic surgical practice.

Conventionally, the split-skin grafts are dressed with non-adherant cotton dressings with or without a tie-over bolster dressing[8]. However, prevention of shearing and/or collection under graft is not always ensured with it. Several attempts have been made in the past towards that end. Aamir *et al* used staplers and plastic syringe to secure a tie-over dressing[27.] This technique was claimed to have reduced the duration of tie-over procedure and was simple and reproducible.

Li-Fu Cheng *et al*[29] and Akihiro Ogino *et al*[30] used rubber bands in place of inelastic sutures to give compression over the graft. Rubber bands were said to give more sustained compression over the graft and were better than sutures in areas like perianal which are particularly difficult to immobilize. They were also said to be amenable for reapplication after opening of dressing thereby allowing early inspection of the graft without losing tie-over compression. Industrial foam and foam rubber has been used to give compression and immobility particularly

for large grafted areas[31] as also fibrin glue which was studied by Dainty LA during vulvo-vaginal reconstruction[32.]

Despite the description of such innovative techniques of dressing and their claimed usefulness, they have not become popular skin-graft dressings. Moreover, these techniques have not been evaluated against conventional dressing techniques in clinical trials to establish their superiority over the latter.

Negative pressure dressing, ever since its inception has been proved to be useful in various clinical situations. Its mechanisms of action and their usefulness on a freshly laid graft were utilized for healing of skin grafts. Addition of negative pressure dressing to skin grafting saw a decrease in incidence of major graft losses and a better quality of graft[,24,25, 27].

Our results demonstrate an increase in the amount of graft take and a better quality of the grafted skin. This result is comparable to similar studies done in the past by various authors. Körber A *et al* showed that negative-pressure dressing improved graft take over chronic leg ulcers[27.] Moisidis E and later Lianos S et al showed in randomized clinical trials that the amount of graft take and quality of the graft improved with application of negative-pressure dressing as compared to conventional dressing[24,25].

The improved amount of graft take can be attributed to various effects of NPD as studied on wounds namely:

- Increase in local blood flow

- ☐ Clearing of discharges
- ☐ reduced bacterial load
- ☐ decreased edema
- ☐ enhanced angiogenesis
- ☐ enhanced epithelialisation
- ☐ Protein and matrix molecular synthesis

In addition, it also helps graft take by:

- ☐ apposing the graft firmly onto the bed particularly on uneven wound surface
- ☐ sucking seromas and hematomas from under the graft
- ☐ preventing shearing of the graft and
- ☐ aiding in immobilizing the part

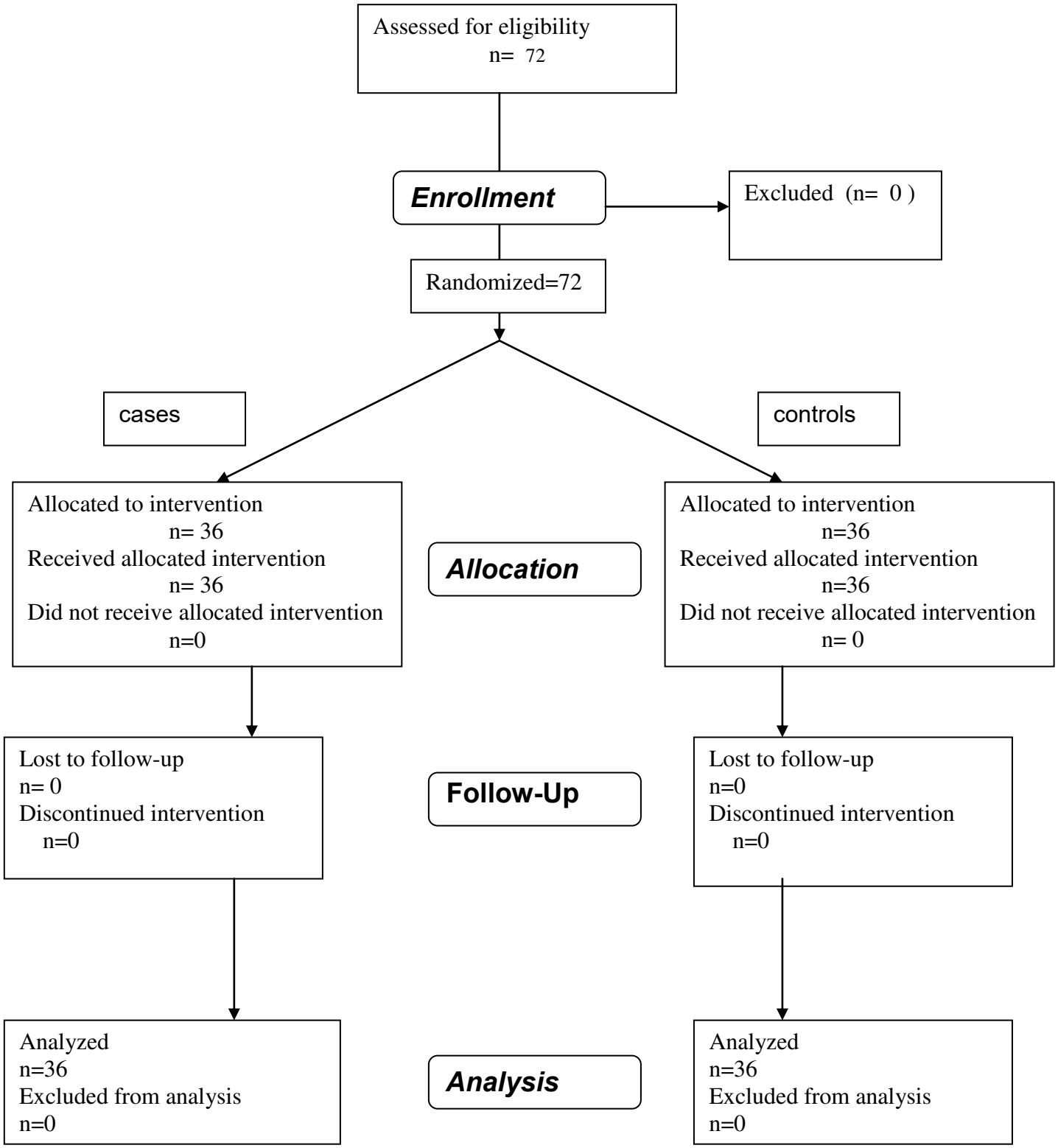
The cost of the negative pressure dressing has been a matter of concern as the commercially available set-up is not always affordable to many patients in a developing country like India. In our study, we have used locally available materials to create a negative pressure dressing and demonstrated that the treatment can be made less expensive and more cost-effective.

SUMMARY

A prospective randomised controlled trial was conducted to find out the effect of negative pressure dressing on healing of split-skin grafts. Written informed consent was taken from the patients. 72 wounds being skin grafted were enrolled and allotted to cases or control groups using computer generated random numbers. The controls received conventional dressing over the split-skin grafts and the cases received a negative pressure dressing. The results were noted at 2 weeks for the amount of graft take and the quality of the grafted skin.

The study revealed a higher average graft take in negative pressure dressing group as compared to the conventional dressing group. The quality of the grafted skin was average in majority of patients in each group but those in above average results had more grafts from the negative pressure dressing group.

THE CONSORT E-FLOWCHART



CONCLUSION

Vacuum assisted closure improves the quantity of graft take and the quality of the grafted skin and hence should be used particularly when the graft bed and/or grafting conditions seem less-than-ideal for a complete graft take. Negative-pressure dressing can be assembled using locally available materials thereby reducing its cost.

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30. Li-Fu Cheng[a,] Jiunn-Tat Lee[a], Trong-Duo Chou[c], Tai-Feng Chiu[c], Tzong-Bor Sun[a], Chien-Hsing Wang[a], Sou-Hsin Chien[b] and Hsian-Jenn Wang[c] xperience with elastic rubber bands for the tie-over dressing in skin graft Burns Volume 32, Issue 2, March 2006, Pages 212-215

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PROFORMA

A Prospective Randomised Controlled Study To Study The Effect Of Negative-Pressure Dressing On Healing In Wounds Covered With Split-Skin Grafts

I

Ia. NAME OF THE PATIENT:

Ib. HOSPITAL NUMBER:

Ic. AGE: Id. SEX:

Ie. ADDRESS:

If. PHONE NO.:

Ig. E-MAIL:

II

IIa. BRIEF HISTORY:

IIb. COMORBIDITIES:

III

IIIa. PART INVOLVED:

IIIb: NATURE OF THE WOUND

IIIbi. FRESH SURGICALLY CREATED

IIIbii. ACUTE WOUND

IIIbiii. CHRONIC WOUND Post-traumatic/post-burn

Diabetic

Venous

Pressure sore

Arterial

other

IIIc. SIZE OF THE ULCER:

IIId. ULCER BED: GRANULATION TISSUE
FASCIA
MUSCLE
CONNECTIVE TISSUE
FAT
OTHERS:

IV

IVa. DATE OF SURGERY:

IVb. DURATION OF SURGERY:

IVc. PERIOPERATIVE COMPLICATIONS:

V Va. TYPE OF GRAFT USED: STSG
FTSG

Vb. MESHING: DONE
NOT DONE

Vc. NEGATIVE-PRESSURE DRESSING USED? YES
NO

Vd. DURATION OF NPD IF USED:

Ve. PATIENT TOLERANCE OF NPD:
WELL-TOLERATED
MILD-MODERATE DISCOMFORT
SEVERE DISCOMFORT

VI

VIa. DAY OF FIRST DRESSING:

VIb. GRAFT TAKE AT FIRST DRESSING:

VII GRAFT TAKE AT 9^{TH} DAY:

VIII RESULT AT 2 WEEKS

QUALITY OF THE GRAFT: ABOVE AVERAGE

AVERAGE

POORER

IX COMPLICATIONS:

X DURATION OF HOSPITAL STAY:

sl no	name	hosp no	age	sex	history	part involved	nature of wound	size	ulcer bed	meshi	use of NPD	tolera	graft take-D9	D14	quality of graft
1	gurunathan	089000c	69	m	cellulitis	foot	i	60	a	y	y	a	100	100	a
2	murugesan	559068d	50	m	rta	foot	c	400	a	y	y	a	95	85	a
3	sabana	464227d	27	f	patches	foot	a	15	d	n	y	a	100	100	a
4	anandkumar	286834d	28	m	rta	leg	c	200	a	y	y	a	90	90	b
5	nisha	283467d	7	f	rta	foot	c	24	f	y	y	b	95	95	b
6	srividya	475692d	2	f	old burn	foot	a	48	d	n	y	b	90	90	b
7	munaf	472001d	16	m	burn	back	d	800	a	y	y	a	98	98	b
8	nanda gopal	615592d	39	m	burn	both arms	d	400	a	y	y	a	100	100	b
9	bela jana	492603d	42	f	spider bite	lt UL	i	600	a	y	y	a	100	100	b
10	madhuri	534461a	51	f	old burn	lt leg	d	9	a	n	y	a	95	70	b
11	ramachandran	690484c	58	m	old trauma	let heel	e	36	a	y	y	a	100	100	a
12	ganesh	669950d	30	m	old acid burn	lt thigh	d	900	a	y	y	a	90	90	b
13	zulfikar	534740d	58	m	old trauma	rtankle	c	48	a	n	y	a	98	98	a
14	naveenkumar	635583d	16	m	electric burn	lt leg	d	150	a	y	y	a	95	95	b
15	pavithra	948794b	11	f	old burn	lt popliteal fossa	b	200	f	n	y	b	100	100	a
16	bhuvaneswari	433338d	26	f	old burn	rt elbow	a	200	d	n	y	a	95	95	a
17	sima chopra	635128d	27	f	old burn	lt axilla	a	900	d	y	y	b	95	95	b
18	venkatesan	632518d	60	m	trauma	lt heel	e	36	a	y	y	a	100	100	a
19	sundaresan	489641d	56	m	rta	lt knee	c	225	a	y	y	a	90	90	b
20	dowlathbanu	493256d	6	f	rta	rt foot	b	64	b	n	y	b	100	99	b
21	selvi	469587d	36	f	rta	rt foot	c	375	a	y	y	a	100	100	a
22	kesavan	492810d	24	m	rta	lt foot	c	48	a	y	y	a	95	95	b
23	saraswati	474465d	56	f	BCC	rt forearm	a	36	c	y	y	a	100	100	b
24	durai	598934D	60	m	diabetic foot BKA	lt leg	e	100	a	y	y	a	95	95	b
25	KANCHAN	598108D	37	m	dermatofibrosarcoma	back	b	49	a	y	y	a	100	100	a
26	DEVINTI DEVI	627784D	40	f	old burn	rt knee	a	300	d	n	y	a	95	95	b
27	VENKATESAN	177029D	47	m	POST-TRAUMATIC CONTRACTU	lt foot	a	48	d	n	y	a	100	95	b
28	PREM CHANDRA PAU	632433D	55	m	diabetic foot	lt heel	i	80	c	n	y	b	0	0	c
29	THEMOTHIOSE	660929D	58	m	old burn	lt foot	e	16	a	y	y	a	100	100	b
30	SITARAM SHARMA	660432D	35	m	rta	rt leg	c	800	a	y	y	a	95	85	b
31	RIYA BASAK	361885D	10	f	old rta	rt foot	a	25	d	n	y	b	85	85	b
32	SHANMUGAM N.	387255D	55	m	inflammation	lt leg	i	80	a	y	y	a	100	100	a
33	DILIP JAISWAL	444767D	30	m	trauma	lt foot	c	20	a	y	y	a	95	95	b
34	SATHYA.S.	457204D	22	f	burn	rt foot	d	100	a	y	y	a	95	95	b
35	SANKAR THAKUR	500670D	16	m	marjolins	rt ankle	a	80	d	n	y	a	95	95	b
36	JANAKI P.	496729D	25	f	burn	rt upper limb	d	1000	a	y	y	a	95	95	b
37	gurunathan	089000c	69	m	trauma	foot	i	60	a	y	n		90	90	b
38	sabana	464227d	27	f	trauma	foot	a	15	d	n	n		80	80	b

sl no	name	hosp no	age	sex	history	part involved	nature of wound	size	ulcer bed	meshi	use of NPD	tolera	graft take-D9	D14	quality of graft
39	sankar thakur	500670d	16	m	old burn	foot	a	84	d	y	n		100	98	b
40	jayanthi	160532d	32	f	old burn	neck	a	50	d	n	n		100	100	b
41	usha devi	642191d	27	m	old burn	neck	a	200	d	n	n		80	70	b
42	vasanthi	326212d	18	f	trauma	foot	a	50	a	d	n		20	0	c
43	munaf	472001d	16	m	burn	back	d	800	a	y	n		98	98	b
44	nanda gopal	615592d	39	m	burn	left forearm	d	400	a	y	n		100	100	b
45	biswanath	594268d	42	m	skull bone infn	scalp	a	150	b	n	n		100	100	b
46	sheela rani	475077b	36	f	reduction mammoplasty wound	both breasts	b	100	a	y	n		100	100	b
47	pramila	619716d	53	f	old burn	rt knee	a	40	d	n	n		100	100	b
48	sony rajak	609380d	30	f	burns	neck	a	75	b	n	n		90	90	b
49	rupa	603220d	24	f	burns	rt leg	d	200	a	y	n		90	90	b
50	hari narayan	566526d	59	m	abscess	lt leg	i	48	a	y	n		90	90	b
51	naveenkumar	635583d	16	m	electric burn	rt groin	d	60	a	y	n		90	90	b
52	saranya	638009d	19	f	rta	rt thigh	c	800	a	y	n		90	90	b
53	prasanta mondal	480229d	61	m	cellulitis	lt leg	i	300	a	y	n		100	95	b
54	SUMANTA	617421D	28	m	ELECTRICAL BURN		c	300	a	y	n		90	90	b
55	SHANKAR SHAW	621425D	27	m	rta	rt heel	a	35	d	y	n		100	95	b
56	DEVINTI DEVI	627784D	40	f	old burn	rt knee	a	300	d	n	n		95	95	b
57	RATHINAM	567039D	65	m	NECROTISING FASCIITIS	lt LL	i	1200	a	y	n		90	85	b
58	PREM CHANDRA PAU	632433D	55	m	diabetic foot	lt heel	i	80	c	n	n		0	0	c
59	ROGER MAYBANK	596828D	77	m	BCC	Left cheek	a	80	c	n	n		90	90	b
60	MOYNUL ISLAM	478983D	27	m	old burn	neck	a	9	d	n	n		100	100	b
61	SANDRA MATHEW	639145D	22	f	Hydradenitis suppurativa	pubis and inguinal	a	100	d	n	n		95	95	b
62	VELU	613341D	37	m	Reverse sural artery flap donor	lt leg	a	200	b	y	n		100	100	b
63	KAMALENA	190276A	30	f	rta	rt foot	c	20	f	n	n		100	100	a
64	GANESAN	669950D	30	m	burns	lt thigh	d	1000	a	y	n		98	98	b
65	GOKULA KRISHNAN	638227D	18	m	rta	rt thigh	c	400	a	y	n		98	98	b
66	PRASANTHI V.	636580D	22	f	old burn	neck	a	150	d	n	n		20	20	c
67	ARCHISMAN CHATTE	647948D	20	m	old burn	lt cheek	a	100	d	n	n		100	100	a
68	DHANAPAL	395111D	55	m	inflammation	rt thigh	i	1000	a	y	n		80	80	b
69	RAMESH	460101D	21	m	burn	rt	d	100	a	y	n		90	90	b
70	SATHYA.S.	457204D	22	f	burn	lt arm	d	100	a	y	n		95	95	b
71	SANKAR THAKUR	500670D	16	m	marjolins	rt ankle	a	80	d	n	n		95	95	b
72	JANAKI P.	496729D	25	f	burn	rt upper limb	d	1000	a	y	n		95	95	b

sl no	name	hosp no	age	sex	history	part involve	nature of w	size
1	gurunathar	089000c	69	m	trauma	foot	i	60
3	sabana	464227d	27	f	trauma	foot	a	15
6	sankar thal	500670d	16	m	old burn	foot	a	84
4	jayanthi	160532d	32	f	old burn	neck	a	50
5	usha devi	642191d	27	m	old burn	neck	a	200
6	vasanthi	326212d	18	f	trauma	foot	a	50
7	munaf	472001d	16	m	burn	back	d	800
8	nanda gop	615592d	39	m	burn	left forearm	d	400
9	biswanath	594268d	42	m	skull bone	scalp	a	150
10	sheela rani	475077b	36	f	reduction n	both breast	b	100
11	pramila	619716d	53	f	old burn	rt knee	a	40
12	sony rajak	609380d	30	f	burns	neck	a	75
13	rupa	603220d	24	f	burns	rt leg	d	200
14	hari naraya	566526d	59	m	abscess	lt leg	i	48
15	naveenkun	635583d	16	m	electric bur	rt groin	d	60
16	saranya	638009d	19	f	rta	rt thigh	c	800
17	prasanta m	480229d	61	m	cellulitis	lt leg	i	300
18	SUMANTA	617421D	28	m	ELECTRICAL BURN		c	300
19	SHANKA	621425D	27	m	rta	rt heel	a	35
20	DEVINTI D	627784D	40	f	old burn	rt knee	a	300
21	RATHINAM	567039D	65	m	NECROTIS	lt LL	i	1200
22	PREM CH/	632433D	55	m	diabetic foo	lt heel	i	80
23	ROGER M	596828D	77	m	BCC	Left cheek	a	80
24	MOYNUI	478983D	27	m	old burn	neck	a	9
25	SANDRA	639145D	22	f	Hydraden	pubis and	a	100
26	VELU	613341D	37	m	Reverse s	lt leg	a	200
27	KAMALEN	190276A	30	f	rta	rt foot	c	20
28	GANESAN	669950D	30	m	burns	lt thigh	d	1000
29	GOKULA K	638227D	18	m	rta	rt thigh	c	400
30	PRASANT	636580D	22	f	old burn	neck	a	150
31	ARCHISM	647948D	20	m	old burn	lt cheek	a	100
32	DHANAPA	395111D	55	m	inflammatic	rt thigh	i	1000
33	RAMESH	460101D	21	m	burn	rt	d	100
34	SATHYA.S	457204D	22	f	burn	lt arm	d	100
35	SANKAR	500670D	16	m	marjolins	rt ankle	a	80
36	JANAKI P	496729D	25	f	burn	rt upper lim	d	1000
			34.31429					
			77					
			16					

ulcer bed	meshing	use of NPD	tolerance	graft take-D	D14		quality of graft
a	y	n		90	90	b	
d	n	n		80	80	b	
d	y	n		100	98	b	
d	n	n		100	100	b	
d	n	n		80	70	b	
a	d	n		20	0	c	
a	y	n		98	98	b	
a	y	n		100	100	b	
b	n	n		100	100	b	
a	y	n		100	100	b	
d	n	n		100	100	b	
b	n	n		90	90	b	
a	y	n		90	90	b	
a	y	n		90	90	b	
a	y	n		90	90	b	
a	y	n		90	90	b	
a	y	n		100	95	b	
a	y	n		90	90	b	
d	y	n		100	95	b	
d	n	n		95	95	b	
a	y	n		90	85	b	
c	n	n		0	0	c	
c	n	n		90	90	b	
d	n	n		100	100	b	
d	n	n		95	95	b	
b	y	n		100	100	b	
f	n	n		100	100	a	
a	y	n		98	98	b	
a	y	n		98	98	b	
d	n	n		20	20	c	
d	n	n		100	100	a	
a	y	n		80	80	b	
a	y	n		90	90	b	
a	y	n		95	95	b	
d	n	n		95	95	b	
a	y	n		95	95	b	
					100		
					0		
					84.26316		

	a	b	c	d	e	f	g	h	i
nature of wound	fresh surg	acute wound	traumatic	burn	diabetic	venous	pressuresore	arterial	post-inflammatory
graft bed	granuln tissu	fascia	muscle	conn tissue	fat	healicoll			
meshing	y	yes							
	n	no							
tolerance	a	well tolerated							
	b	mild to moderate discomfort							
	c	severe discomfort							
quality of graft	a	above average							
	b	average							
	c	poor							
sex	m	male							
	f	female							