

COMPARATIVE EVALUATION OF EFFICACY OF PURE COLLAGEN TYPE I BASED MODERN DRESSING WITH CONVENTIONAL DRESSING IN THE TREATMENT OF BURN AND DIABETIC FOOT ULCER.

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Abstract:-

Aim: To evaluate the significance of introducing an absorbable collagen type-I dressing in the management of Burn wound and Diabetic Foot wound.

Background: A wound may be explained in numerous ways; either by its etiology, by anatomical location, by whether it is acute or chronic, by the method of closure, by its presenting symptoms or indeed by the appearance of the predominant tissue types in the wound bed. The variety of wound types have resulted in a wide range of wound dressings. In order to offer the most excellent treatment options, these challenges need to be identified and overcome by using the most appropriate dressings and treatment regimens available.

Methods: Total no. of 41 Patients was treated with SkinTemp™ II and Medifil™ II. Case report from (CRF) is an observation study data that was undertaken on injured patients with a variety of wound types are presented. Patients were classified in to two groups “*HBS-SRK Group*” and “*Conventional Group*”.

Results: The beginning of dressings with SkinTemp™ II and/ or Medifil™ II was linked with fall in pain during the surgery and re-dressing. The standard duration for appearance of in good physical shape of granulation tissue over the wounds that were treated with collagen dressing (SkinTemp™ II and Medifil™ II) was 8-12 days while conventional dressing took more than 30 days for same granulation formation.

Key words: Diabetic foot ulcer, SkinTemp™ II and Medifil™ II, Collagen Type-I, Wound.

Introduction

All through the last decade, a variety of novel dressing materials developed, namely calcium alginate, hydro-colloid membranes and fine mesh gauze. These have one drawback in that they turn out to be permeable to microorganisms. On other hand Biological dressings like collagen, produce the most physiological crossing point between the wound surface and surroundings, and these are also avoid the permeability to micro-organisms [1, 2,3]. Collagen dressings have many supplementary advantages in excess of usual dressings in terms of effortlessness of application and being natural, non-immunogenic, non-pyrogenic, hypo-allergenic, and pain-free [4,5,6]. The present study has been conducted to compare the efficacy of SkinTemp™ II and Medifil™ II (collagen dressing) with that of conventional dressing materials like oxidized regenerate cellulose, silver sulfadiazine, nadifloxacin, povidone iodine or honey, in the management of chronic wounds including those due to burns or diabetic foot ulcer. Collagen is the unique, triple helix structured protein molecule, which forms the major part of the extracellular dermal matrix (ECM), together with the glycosaminoglycans, proteoglycans, laminin, fibronectin, elastin and cellular components[7,8,9]. Collagen is the most abundant protein in animal tissues and accounts for 70–80% of the dry weight of the dermis [10,11]. Collagen type I comprises approximately 70% of collagen in the skin [12,13]. The principal function of collagen is to act as a scaffold in connective tissue, mostly in its type-I. In addition together to being the main component of scar tissue, collagen has a key role in below [14,15,16] –

1. The control of the inflammatory response to injured site and subsequent repair with functions that influence cellular mitogenesis, differentiation and migration.
2. Protein synthesis in the extracellular matrix (ECM)
3. Synthesis and release of inflammatory cytokines and growth factors
4. Interactions between enzymes which remodel the ECM, including matrix metalloproteinases (MMPs) and their tissue inhibitors (TIMPs).

Wound healing is a multifaceted and active process with the wound surroundings changing with the changing health condition of the human being [17,18]. The knowledge of the physiology of the normal wound healing path through various phases of like as hemostasis, inflammation, granulation and maturation provides a structure for an understanding of the basic principles of wound healing. All phase of wound healing are different, although the wound

healing process is continuous, with each phase overlapping the next [19,20]. For the reason that successful wound healing requires adequate blood and nutrients to be supplied to the situation of injury, the overall

health and nutritional status of the patient influence the outcome of the injured tissue. Through this understanding the health care professional can develop the skills required to care for a wound and the body can be assisted in the complex task of tissue repair [21].

There are three basic principles which underlie wound healing.

1. Identify and control as best as possible the underlying causes.
2. Support patient centered concerns
3. Optimize local wound care.

Excerpted from Wound Bed Preparation, outlines an algorithm that provides a framework for chronic wound management fig-1.

The Ideal Dressing Turner described the ideal dressing as having the following characteristics [22]

1. Removes excess exudates and toxins
2. High humidity at the dressing wound interface
3. Allows for gaseous exchange
4. Provides thermal insulation
5. Protects against secondary infection
6. Free from particulate and toxic components
7. No trauma with removal.

Protocol-

We composed the report of the patients with acute as well as chronic wounds on different parts of the body and of a variety of etiologies, treated in different hospitals with their concern department with either collagen dressings or one of the conventional dressing materials, over a period of time (approx 300 days). During this study the total numbers of 85 patients were treated. The patients with co-morbidities that could grossly affect the wound healing like uncontrolled diabetes foot, burn (flame, chemical and electrical) were included. For the sake of study the patients were separated into two groups; 'HBS-SRK Group' and 'Conventional group'. The recorded data from the patients' files (Case Report form) regarding characteristics of all wounds as size, edge, floor characteristics, slough, granulation tissue, pathogenic organisms and wound swab or pus culture sensitivity results were noted and analyzed. Wound swab or pus culture was done every three to five days or when specifically required. Collagen Sheets with

suitable sized were selected. Remove

Dalnet (it is another nylon film attached with SkinTemp™ II sheet) from Collagen sheets and were rinsed in normal saline before application. Sheets were applied confidently so as to cover the whole raw area of wound/ulcer. Care should be taken to remove delnet and any air bubbles. This can be making easy by using the back of the thumb-forceps to apply a little pressure from one end of the dressing to the other. The movement of the forceps should be just similar to the movement of a knife while applying butter on a toast. Frequency of dressing was depended on the condition of the wound.

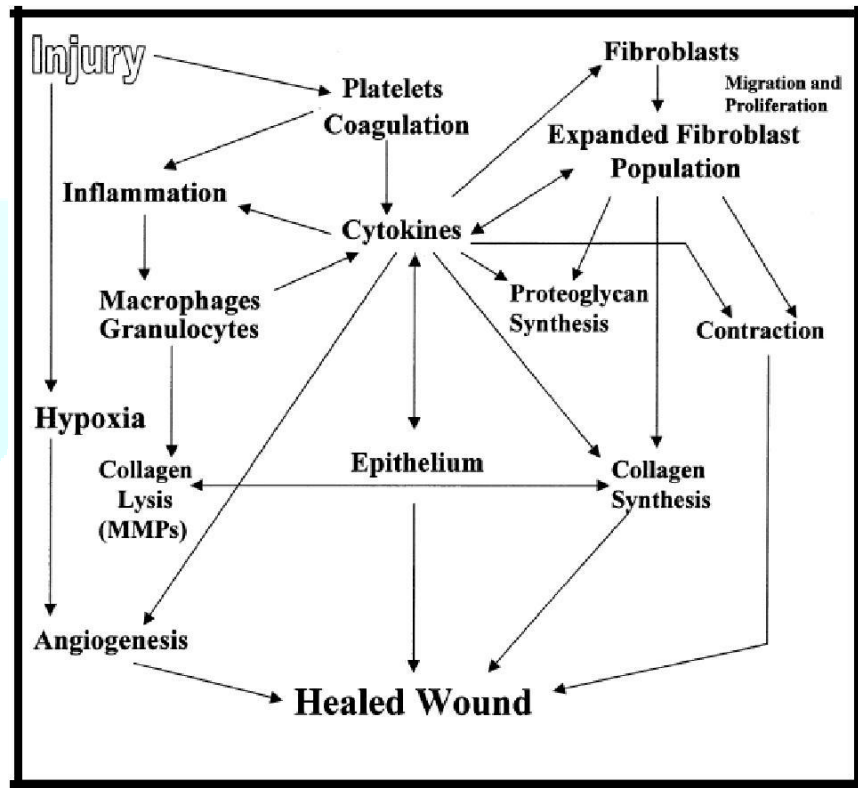


Figure 1- The acute wound-healing cascade. The progression of acute wound healing from hemostasis to the final phases of remodeling is dependent on a complex interplay of varied acute wound-healing events. Cytokines play a central role in wound Healing and serve as a central signal for various cell types and healing events.

Wounds of the patients in the ‘Conventional group’ were dressed with povidone iodine, honey, ORC etc. In few conditions both the groups were treated with antibiotics based on the

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pus culture sensitivity report. Response to the treatment and patients' outcome were noted in terms of progression of wound healing, granulation tissue formation, changes in edges of wounds and need of skin grafts. The results were analyzed using 'Mann-Whitney test' and 'Pearson Chi-Square test' depending on the type of data.

Table 1- Patients characteristics and groups chosen for the study.

S.No.	Patient characteristics		Collagen Group		Conventional Group	
			No. of patients	% in group	No. of patients	% in group
1	Sex	Male	25	61.00	30	69
		Female	16	39.00	14	31
2	Type of wound	Post-burn	15	36.59	15	34.09
		Diabetic Foot	19	46.34	20	45.45
		Post-traumatic	7	17.07	10	22.73
3	Age	<20 Years	12	29.27	7	15.91
		20-40 Years	11	26.83	17	38.64
		>40 years	18	43.90	20	45.45

Table 1- showing two group of patients- HBS-SRK Group and Conventional group. Male and female both were selected for treatment. Out of 85 patients 39 was Diabetic foot ulcer class and 30 patients were post burn class, 38 patients were over 40 years old.

Table 2- Response to the treatment

Treatment response	Collagen Group (n=41)	%	Conventional Group (n=44)	%	values
Sterile wound swab culture at two weeks	28	68	19	43	*0.158
Sterile wound swab culture at four weeks	37	90	28	64	
Avg. time for healthy granulation to appear	8 days		13 days		**-.0179
Complete wound closure at six weeks	17		9		**-. 0.11

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At eight weeks, wounds with >75% closure	34		29		** - 0.03
Wounds that required SSG	6		11		** - 0.11

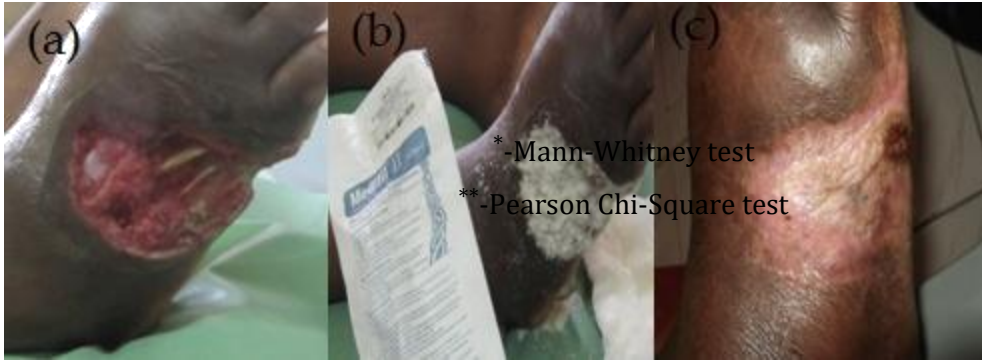


Figure 2- Showing condition of Diabetic foot Ulcer wounds (A 58 years Old female Patient admitted in the Military Hospital, This picture shows exposed of Bone and Tendons.) since day-1 to final wound stage. (a)- Day-1 wound condition infected and bad smell (b) after proper debridement application of Medifil™ II granules to cover entire wound area. (c) Resulting wound condition after few no. of dressing with Medifil™ II Granules and SkinTemp™ II Sheets.



Figure-3- Diabetic Foot Ulcer (a 55 Years Old female patient from Chennai) wound history suffered from last 8 years. (a)& (b) are the different views front and bottom respectably of right leg, very infected yellowish colored and exposure of tendons, (c) after treatment with Medifil™ II and SkinTemp™ II showing clear healthy granulation in short period of time, (d)&(e)- complete closer of wound with both of view.

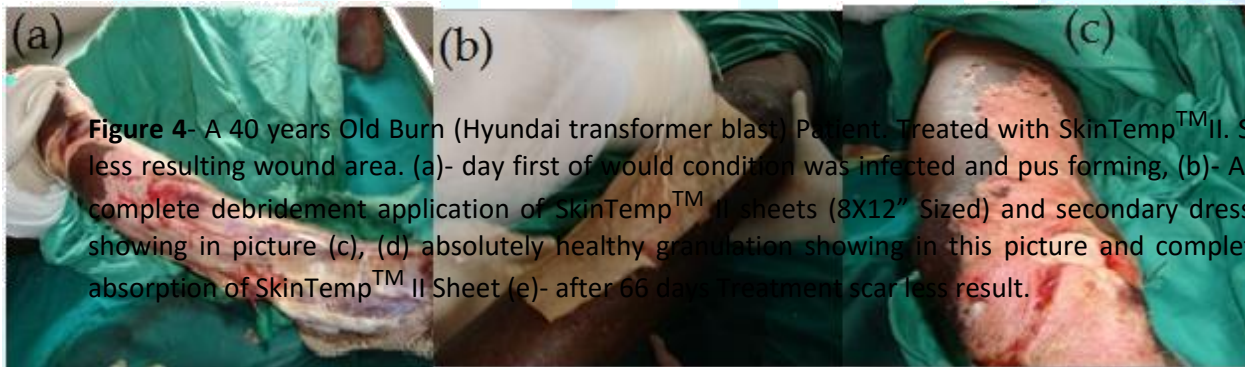


Figure 4- A 40 years Old Burn (Hyundai transformer blast) Patient. Treated with SkinTemp™ II. Scar less resulting wound area. (a)- day first of wound condition was infected and pus forming, (b)- After complete debridement application of SkinTemp™ II sheets (8X12" Sized) and secondary dressing showing in picture (c), (d) absolutely healthy granulation showing in this picture and completely absorption of SkinTemp™ II Sheet (e)- after 66 days treatment scar less result.

Figure-5 Burn Wound the patient was 24 years old male. Entire right lower leg was exposed to the thermal damage (a) show burn wounds in patient before commencement of treatment. Photographs show severity of the accident. Multiple wounds due to burn injury occurred predominantly on the limbs. The photo (b) shows treatment using SkinTemp™ II and Medifil™ II,

Figure (c) shows the wound after 3 weeks of treatment. It shows epidermis on the way restoration.

Results

A total of 85 patients were treated in this study. Different etiologies of chronic wounds were recognized: decubitus ulcer, post-traumatic wound and post-burn. Out of 85 patients, 19 (22%) belonged to the age group 01-20 years, 28 (32%) to 20-40 years, and 38 (45%) were more than 40 years of age. 55 (65%) were males and 30 (35%) were females. There was no significant difference in the age and sex distribution of patients and etiology of the wounds in both groups.

The standard duration for appearance of in good physical shape of granulation tissue over the wounds that were treated with collagen dressing (SkinTemp™ II and Medifil™ II) was 8-10 days. The post-infective wounds healed fastest (average time to healthy granulation tissue: 7 days) and the diabetic foot wounds slowest (average time to healthy granulation tissue: 13 days).

In the 'conventional group' the average time for appearance of healthy granulation tissue was 18 days. In this group, the post-traumatic wounds healed fastest (average time to healthy granulation tissue: 13 days) and diabetic foot wounds slowest (average time to healthy granulation tissue: 35 days) When the wounds of the patients in both groups were compared etiology-wise, each type of wound treated with collagen dressing had lesser average time and frequency of dressing for appearance of healthy granulation tissue, than the same type of wound treated with conventional dressing material.

It was found that out of 41 patients of the HBS-SRK Group 35 (85%) wounds showed complete closure with collagen dressing in six weeks or lesser time, and rest 5 more wounds showed 75-100% closure in the next two weeks. Collagen sheets in these patients were found almost fully incorporated in the wounds. The remaining 1 (diabetic foot) achieved less than 75% closure even at the end of six weeks and underwent split-skin grafting (SSG). In the conventional group, a total of 32 patients (72%) showed 75-100% closure at the end of the eighth week while the remaining 12 (four- diabetic Foot) were less than 75% closed and thus required SSG. Therefore, although a greater number of collagen-treated wounds achieved more than 75% healing after eight weeks (52 versus 48); the difference was not statistically significant ($P= 0.15$). However, only eight collagen-treated wounds required SSG as compared to 12 wounds treated with other materials ($P= 0.179$).

Discussion

Chronic wounds take a longer time for healing as all chronic wounds have elevated levels of matrix metalloproteinase's, which result in increased proteolytic activity and inactivation of the growth factors involved in the wound-healing process. Thus, a chronic wound due to any cause is a situation that needs the use of a temporary cover for the raw surface. The use of collagen based dressing (SkinTemp™ II and Medifil™ II) has been found to inhibit the action of metalloproteinases. Collagen is a biomaterial that encourages wound healing through deposition and organization of freshly formed fibers and granulation tissue in the wound bed thus creating a good environment for wound healing. Collagen sheets, when applied to a wound, not only promote angiogenesis, but also enhance body's repair mechanisms. While acting as a mechanical support these reduce oedema and loss of fluids from the wound site, along with facilitation of migration of fibroblasts into the wound and enhancing the metabolic activity of the granulation tissue. Moreover, it is easy to apply and has the additional advantage of stopping bleeding. Other commonly used biological dressings include amniotic membrane and homograft skin. SkinTemp™ II and Medifil™ II, has a low price and provides good wound coverage and has distinct advantages compared with other biologic dressings. Although the risk of transmission of viral infections e.g. hepatitis, syphilis and HIV is an important concern with the use of amniotic membrane, but with routine screening of each and every patient this risk can be easily avoided. The homograft skin is another very good alternative, but causes the obvious problem of management of additional wounds. Other uses of collagen sheets in cutaneous surgery are a reasonably simple option for initial temporary coverage, and definitive reconstruction of full-thickness scalp defects created after resection of malignant tumors of the scalp. As such, these may also be useful to cover the defects in oral mucosa, bones and tendons, and donor area in skin grafting procedures where large grafts are harvested.

In this study, significantly more collagen-treated wounds were rendered sterile as compared to those treated with conventional dressings, after two weeks ($P= 0.11$) and four weeks ($P= 0.03$) of treatment. This is due to the fact that collagen dressings cover the wound and act as an effective barrier to infection. Healthy granulation also appeared significantly earlier in collagen-treated wounds as compared to conventionally treated ones ($P=0.03$). The bacterial colonization of a wound may progress to an active infection in a wound and therefore

affect healing. Thus, regular surveillance of the bacterial profile and their antibiotic susceptibilities should also be a part of the overall management strategy of wound care units, so as to guide appropriate antibiotic therapy while the dressings are doing their part. In the present study, this was done every three to five days or when specifically indicated.

Regarding healing of the Burn Wounds, another study is running by Dr. Ajay Lunawat Head-Burn Surgery Arvindo Hospital Indore India for 250 patients. Although a subjective finding, most patients with collagen dressing reported to enjoy early and greater degree of mobilization and more comfort as compared to those who were applied honey, silver-sulphadiazine cream or providone iodine ointment etc.

Lastly, the present study has a few drawbacks. First, it is a retrospective study. The ideal scenario is to treat and compare two different wounds one with and the other without SkinTemp™ II and Medifil™ II in the same patient in a prospective study. Also, this study did not include an important and more useful issue of the cost and availability of SkinTemp™ II and Medifil™ II. These issues warrant further randomized studies. Furthermore, although in the 'HBS-SRK group' SSG was needed for significantly lesser number of patients, this is based on the findings of a small number of patients. Thus this result cannot be generalized with high confidence. Therefore, the need for further randomized controlled studies that have a large number of patients, and are accurately designed has to be recognized from the present study

Conclusion-

Wound healing proceeds rapidly and competently in a physiologic environment conducive to tissue regeneration and repair. Nutritional requirement of patients at the time of trauma or surgery influences the biochemical processes necessary for the phases of normal healing to occur. Undernourished or malnourished individuals heal less efficiently and are at greater risk for complications during and after surgery. Part of treating the whole patient and not just the "hole in the patient" is appreciating the complex interactions and the nutrients involved in the wound-healing process. The relationship between malnutrition and poor wound healing is well documented, while the impact of optimal levels of dietary and supplemental nutrient intakes for wound healing is relatively unknown. Promotion of good nutrition is recommended, particularly in populations at risk for marginal and frank nutritional deficiencies, including the elderly diabetic foot elderly patients.

Above evidence exists that collagen Type I is beneficial to wounded or surgical patients; however. More extensive, well-defined, blinded clinical trials to evaluate the safety, efficacy of collagen based dressing (Skin TempTM II and MedifilTM II)

Collagen Type I dressings are soft, flexible and absorbable. This dressing reduce inflammation, relieved wound pain, improved patient comfort, effectively absorbed exudates (only excessive concentration), softened fibrin, decreased the need for debridement, prohibited maceration and reduce the frequency of dressing changes obligatory in the surgery. These products are also provided a quicker healing rate than skilled with other conventional dressing types for similar wounds. Only 6 dressings of SkinTempTM II /MedifilTM II were used in the course of this wound's (non healing Diabetic foot Ulcer) management. SkinTempTM II and MedifilTM II both are cost efficient and time efficient. The quick and easy "on and off" change protocol of SkinTempTM II decreased the burn wound's exposure to air during the dressing change process which reduced the risk of possible infection. SkinTempTM II as well as medifilTM II either as available in the market or after making thick slurry in normal saline were excellent dressings to use on this second-degree burn. Burns are some of the most painful wounds: a dressing that decreases pain and decreases the time required for healing is important to both the patient and to the clinician.

Acknowledgement-

Authors acknowledge that the above study is genuine and real data were compiled in this paper. Author thanks to all Hospitals and their doctors to support us.

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