

# The Use of A PVA Foam Dressing Impregnated with Methylene Blue and Gentian Violet on Skin Tears: A Pilot Study

Author: **Jeanne Alvarez, MSN, FNP, CWS** Assistant: **Heather Petley, MA, SN** (University of Maine)

## Abstract

There are more than 1.5 million skin tears reported on institutionalized Americans and the numbers continue to rise as the baby boomers get older. Skin tears disrupt the skin integrity, increase the risk of infection, and cause distress to those involved. This pilot study examined various skin tears occurring at two medical facilities over a 6-week period. The study evaluated the effectiveness of a PVA Foam Dressing Impregnated with Methylene Blue and Gentian Violet (Hydrofera Blue™), in the treatment of skin tears. The focus was on 1) time to closure, 2) pain levels, and 3) incidence of infection. The study showed that this wound dressing is a highly effective dressing material for skin tears of all categories. Skin tears of more serious categories showed a significant improvement in healing times. There was a noted decrease in reported pain within 24 hours, and there were no reported infections.

## I. Introduction

A skin tear is defined as a traumatic wound resulting in the separation of the dermis from the epidermis at the basement membrane level. In 1999, it was estimated that there were approximately 1.5 million skin tears of elderly patients in U.S. nursing homes. With the noted increase in the elderly population in the U.S., one can extrapolate that this problem will increase significantly as the "baby boomer generation" ages. By the year 2030, 8.1 million Americans will be categorized as the "old-old" – those greater than 85 – and this will be our fastest growing segment of the population. It is the aging skin of the "old-old" on which most skin tears occur.

## II. Purpose

The purpose of this study was to determine the effectiveness of a PVA foam wound dressing impregnated with methylene blue and gentian violet, in the treatment of various skin tears. The focus was on 1) time to closure, 2) pain levels, and 3) incidence of infection.

## III. Methods






Data was obtained from a 100-bed long-term care facility and from other patients who reported to an outpatient family practice office for evaluation of skin tears. This study took place over a six-week period in February/March 2004. An evaluation form was provided on which the examiner would document the date, location, skin tear category, wound measurements, cognitive ability, pain scale score, and any signs and symptoms of infection.

## IV. Procedure

Attending caregivers first identified patients having one or more skin tears. These patients' skin tears were then classified into the appropriate Payne-Martin skin tear category that best described each tear. The staff then cleansed the wounds with soap and water, irrigated the wounds and skin flaps with saline, and approximated the wound margins if necessary. Measurements of overall skin tear sizes and gap sizes were obtained and initial photos were taken. Using this PVA Foam Wound Dressing Impregnated with Methylene Blue and Gentian Violet (Hydrofera Blue™), the dressing was cut to fit over the wound bed and wound edges. The dressing was moistened with normal saline and the excess saline was squeezed out. The moistened dressing material was then placed over the wound and the entire wound site was covered with a film dressing (Tegaderm Film Dressing™). The dressings were removed after 24 hours for the first assessment, photos were taken, and dressings were reapplied using the same protocol. The dressings were then changed every three days until healed. This protocol was implemented to follow the course of healing for these wounds.

## Payne-Martin Skin Tear Categories:

In the late 1980's, the Payne-Martin Classification for Skin Tears assessment tool was developed, it was revised in 1993. This tool divides skin tears into three categories, with subdivisions in the first two categories.

|   |   |  |   |  |
|---|---|--|---|--|
| <b>Category 1</b><br><b>Skin Tears Without Tissue Loss</b>      |   | <b>Linear type:</b><br>the epidermis and the dermis have been pulled apart |  | <b>Flap-type:</b><br>the epidermal flap completely covers the dermis to within 1mm of the wound margin |
| <b>Category 2</b><br><b>Skin Tears With Partial Tissue Loss</b> |   | <b>Scant tissue loss:</b><br>25% or less of the epidermal flap is lost     |  | <b>Moderate to large tissue loss:</b><br>more than 25% loss of tissue                                  |
| <b>Category 3</b><br><b>Epidermal Flap is Completely Gone</b>   |  |  | <b>Epidermal flap is lost</b>   |  |

**Table 1. Characteristics of study participants from long-term care facility and outpatient clinic**

|                               |  |
|-------------------------------|--|
| Mean Age                      | 76 years (Range 61-92)   |
| Gender                        | 80% female<br>20% male   |
| Most Common Medical Diagnosis | DM, Dementia, CAD, PVD, HTN, COPD, Hyperlipidemia, Hypothyroidism, Osteoporosis, Congestive Heart Failure, Anemia, Depression, Anxiety, Multiple Sclerosis, Polymyalgia Rheumatica, Glaucoma |

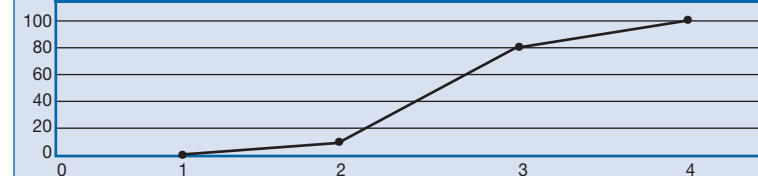
**Table 2. Skin Tear Classifications, Number of Tears, Wound Area, Location, and Days to Healing**

| Wound Classification         | Number of Tears | Wound Area (cm <sup>2</sup> ) | Location of Wound | Days to Healing |
|------------------------------|-----------------|-------------------------------|-------------------|-----------------|
| Category 1, Linear           | 1               | 12.0 cm <sup>2</sup>          | Forearm           | 8 days          |
| Category 2, <25% tissue loss | 2               | 0.45 cm <sup>2</sup>          | Knuckle           | 4 days          |
| Category 2, >25% tissue loss | 1               | 5.00 cm <sup>2</sup>          | Shin              | 25 days         |
| Category 3                   | 3               | 2.42 cm <sup>2</sup>          | Shin              | 21 days         |
|                              |                 | 0.36 cm <sup>2</sup>          | Forehead          | 7 days          |
|                              |                 | 1.00 cm <sup>2</sup>          | Knee              | 28 days         |
|                              |                 | 13.5 cm <sup>2</sup>          | Shin              | 10 days         |

## Wound Photos – Before and After Treatment



## Endotoxin Binding by Hydrofera Blue™



## What is Hydrofera Blue?

**Hydrofera Blue:** is A PVA (polyvinyl alcohol) foam impregnated with methylene blue and gentian violet

**Observations of Hydrofera Blue:** effective against both gram positive and gram negative organisms, including MRSA and VRE, pseudomonas aeruginosa, yeast

- decreases the bioburden of the wound bed
- binds 100% of endotoxins in 4 hours
- inactivates some viruses
- flattens epibole
- decreases inflammation
- reduces pain significantly within the first few days of therapy, probably related to the binding of the endotoxins
- has slight negative pressure properties
- reduces fibrin covering on the wound surface
- is soft and comfortable
- maintains moist wound therapy
- has a Medicare HCPS code and is reimbursable
- requires a secondary dressing

I have used this product successfully on many types of wounds, including: pressure ulcers, venous stasis ulcers, diabetic ulcers, arterial ulcers, pyoderma gangreosum, atypical wounds, spider bites, chemical burns, pilonidal cysts, surgical sites, 1st and 2nd degree burns, biopsy and excision sites, vasculitic wounds, infected wounds, poison ivy, severe candidias infection, and non healing tumor sites. To date I have not had any allergic reactions to this product.

It is manufactured by Hydrofera, Willimantic, Connecticut.

## V. Results

There were a total of eight skin tears on five patients reported during the study. The patients' mean age was 76 years with a range from 61-92 years. All patients exhibited significant co-morbidities such as Dementia, Chronic Obstructive Pulmonary Disease, Diabetes, Coronary Artery Disease, Hyperlipidemia, Osteoporosis, Congestive Heart Failure, Anemia, Depression, Anxiety, Multiple Sclerosis, Polymyalgia Rheumatica, Glaucoma, Hypothyroidism, Hypertension or Peripheral Vascular Disease. All patients were found to be on multiple medications, some of which are known to inhibit wound healing. All patients were noted to have thin and fragile skin. The mean average for closure of the skin tears was fourteen days with a range from four to twenty-eight days. Three of the five patients complained of significant pain in the skin tear sites on day one, with the reported pain ranging from 7-10 on a 0 (no pain) - 10 (severe pain) scale. Within twenty-four hours of the application of Hydrofera Blue™, all patients reported no pain at the site. Four of the seven skin tears healed in ten days or less. The three skin tears that required 21-28 days to heal were one category 2 > 25%, one category 2 <25%, and one category 3; these wounds measured 2.42cm<sup>2</sup>, 5.0cm<sup>2</sup>, and 13.5cm<sup>2</sup>, respectively. These wounds were the larger wounds included in the study and were of the more significant skin tear categories.

## VI. Discussion

This study showed that the use of a PVA Foam Dressing Impregnated with Methylene Blue and Gentian Violet (Hydrofera Blue™, Hydrofera LLC) and a film cover dressing (Tegaderm Film Dressing, 3M) has substantially improved healing rates for the more serious skin tear categories. When comparing healing rates for various categories of skin tears, other studies have shown category 1 healing rates from 3-22 days, category 2 healing rates from 10-39 days, and category 3 healing rates from 8-51 days.<sup>7,8</sup> This study showed a healing rate of 8 days for category 1, 4-25 days for category 2, and 7-28 days for category 3 skin tears.

This dressing had a generally superior healing rate to those observed in other studies, and it is particularly effective in pain reduction within 24 hours of application. In our study's patients, there were no reported infections. The one skin tear that was excluded from the data because it was started on a different treatment protocol was located on the shin and was 78cm<sup>2</sup>. On day eighteen of this wound, debridement of the nonviable flap was completed. There were noticeable signs and symptoms of infection present at this time, including increased pain, erythema, the development of an odor, and an increased exudate. The decision was made to begin using the PVA Foam Dressing Impregnated with Methylene Blue and Gentian Violet on this skin tear and within twenty-four hours, the patient reported no further pain at the skin tear site. This wound closed in 35 days using this wound treatment protocol for skin tears. This dressing material also controlled infection, and the patient did not require oral antibiotics. This observation supports previous findings that suggest this wound dressing is an effective antimicrobial agent for many organisms. This PVA Foam Dressing Impregnated with Methylene Blue and Gentian Violet can be used on infected wounds, eliminating the need for oral antibiotics in many cases. The use of topical treatments for infected wounds will help in the reduction of the overuse of systemic antibiotics.

## VII. Conclusion

This pilot study, although limited to seven skin tears, showed this PVA Foam Dressing Impregnated with Methylene Blue and Gentian Violet (Hydrofera Blue™) to be a highly effective wound care product for the treatment of skin tears of all categories. Healing times for more serious skin tears were significantly improved using this product. There was a noted decrease in pain within 24 hours of dressing placement and there were no infections reported. A larger clinical study would be helpful in substantiating the data of this study; a comparative study of this product to others with a cost analysis would be beneficial in aiding facilities to make decisions on protocols for skin tears.

Hydrofera LLC, provided the product of Hydrofera Blue for this clinical study.

### Comparison Studies:

- Study 1: Edward, Gaskill, & Nash International Journal of Nursing Practice, 1998; 4:24-32
- Study 2: Thomas, Goode, LaMaster, Tennyson & Parnell. A Comparison of an Opaque Foam Dressing Versus a Transparent Film Dressing in the Management of Skin Tears in Institutionalized Subjects, 1999. 45:6, 22-26.
- Study 3: Payne & Martin. Skin Tears...The Epidemiology and Management of Skin Tears in Older Adults. 1990, Jan/Feb 27-37.

To obtain a copy of this study in its entirety, please contact Hydrofera.

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