PUSH

Pressure Ulcer Supplement for **Healing**

Wound Trial 2016

Study was performed in a 160 bed long-term care facility in Upstate NY

Global Health Products, Inc.

Introduction

In today's aging society, more elderly people are requiring long term care in either a hospital or a nursing home. When our elderly become bedridden or immobile, the ability to change posture or positioning brings upon higher risk to form pressure ulcers. As we age, our skin becomes dry and less elastic causing skin to easily tear or shear. Proper nutrition is another factor in combating overall health and skin integrity.

The treatment of pressure ulcers has been centered on preventing the wound from becoming chronic. Treatments are established to keep the wound bed clean and boost nutrition levels. Our study looks at "internal wound healing" and the adding of a specific patented blend of dipepetide into the wound patient's diet.

PUSH (patented di-peptide) was developed in hope that it would become a functional component contributing to healing pressure ulcers compared to the standard approach of feeding patients the standard amino acid blend commonly found in protein supplements.

PUSH Absorption

PUSH derived dipeptides and tripeptides (such as hydroxyproline (Hyp)) are detected in human blood after PUSH is orally taken. This chapter discusses the PUSH dipeptides manufactured by Global Health Products Inc. The pig hide –derived collagen blend is characterized by an average molecular weight of 1300 and contains dipeptides (such as proly-hydroxyproline and hydroxyproyl-glycine). To evaluate the kinetics of peptides entering the bloodstream after PUSH intake, absorption tests were conducted in 5 male volunteers. After having them intake 8g of PUSH, their blood was sampled from the vein at 0, 0.5, 1, 2 and 4 hours to measure (Pro-Hyp and Gly peptides) The results found that Pro-Hyp transferred to the blood the most followed by Hyp-Gly. As for absorption behavior of Pro-Hyp, the maximum blood concentration was reached at about one hour after which the concentration declined gradually. Furthermore, a rat experiment showed that Pro-Hyp in the blood stream reached the dermis in 30 minutes.

The physiological functions of Pro-Hyp on cells (included chemotaxis) by which fibroblasts cells gather, promoting cell multiplication and promotion of hyaluronic acid production. Hyp-Gly has been demonstrated to significantly enhance the multiplication generated by Pro-Hyp in the first-generation fibroblast. In conclusion, Pro-Hyp and Hyp-Gly absorbed after PUSH intake are believed to repair damaged skin tissues and promote remodeling.

Oral intake of PUSH is also expected to demonstrate strong effects on the treatment of pressure ulcers, discussed in the following chapters of this study.

PUSH Supplement Trial

Start Date: 6/13/16
End Date: 9/4/16

Overview

The purpose of this study was to see what affect the PUSH Supplement has on wound healing. The study was done over the course of 12 weeks at a 160 bed nursing facility in upstate New York on a wide variety of wound types. By comparing the wound data of the facility for the time period before, during and after the trial, we will show how PUSH helped increase wound healing for the patients in this study.

Trial Parameters

All patients with existing wounds at the start of the trial and new wounds during the trial were put on the PUSH Supplement. Each patient was to take 1 serving of PUSH mixed into 2-3oz of water BID for the duration of the trial. Servings were mixed and administered by licensed RN's employed by the test facility.

Tracking Progress During the Trial

Wounds are required (by law) to be assessed by the facility every 7 days. All data was collected through the facilities wound assessment software. This software provides reports on all aspects of each wound including wound type, location, measurements, wound bed tissue type, drainage and notes. Every Tuesday, skin rounds are performed by the facility's wound assessment team consisting of the medical director, facility skin nurse and nursing staff from each unit. The new wound assessments were entered into the assessment program to be stored and tracked. Reports can be generated showing the progress of each wound and the overall performance of the facility. The number of existing wounds at the start of the trial was recorded, along with the average Pressure Ulcer Score for Healing and the cost of dressings ordered for those wounds each week. Each week of the trial this data was recorded to document wound progress over the 12 week time frame. We also looked at the average wound heal times for the facility from the previous 48 weeks (broken out into 12 week periods).

PUSH Supplement Results

Number of Wounds

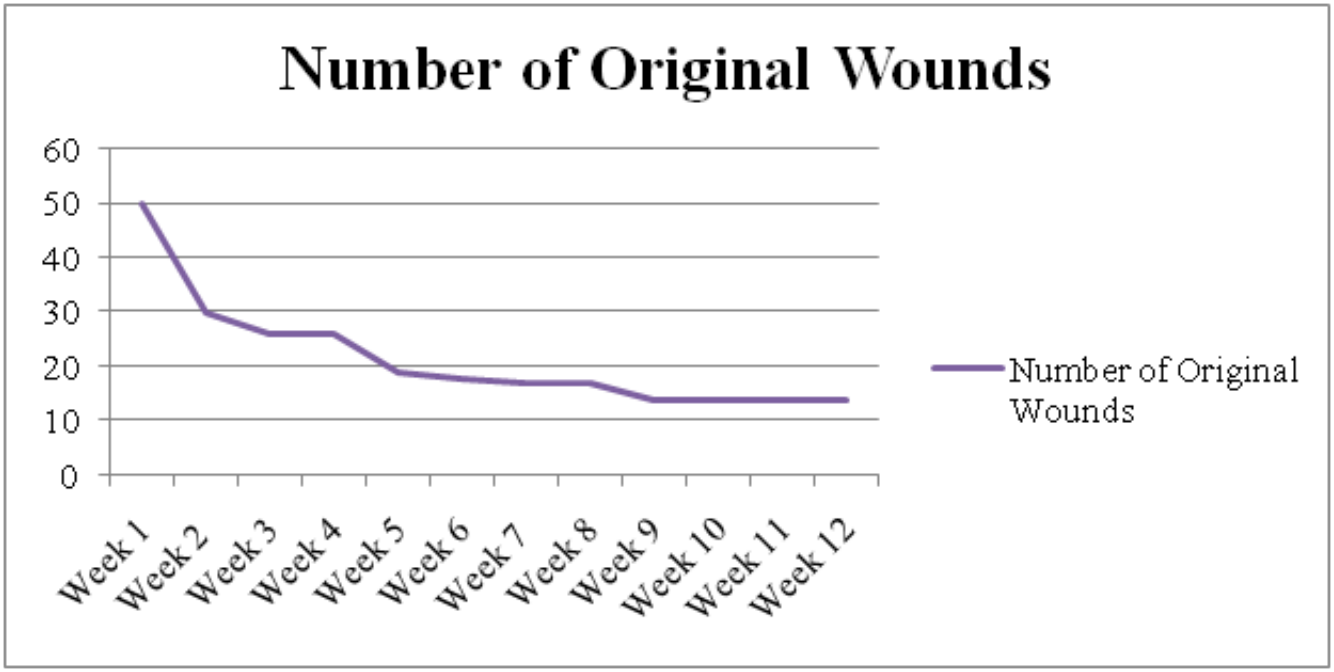
At the start of the trial the test facility had a total of 50 wounds consisting of:

Type of Wounds	Total Wounds
Surgical	2
Stage 4	2
Stage 3	1
Stage 2	3
Stage 1	1

Type of Wounds	Total Wounds
Unstageable	17
Venous Ulcer	5
Abrasion	2
Abscess	1
Blister	2

Type of Wounds	Total Wounds
Edema	2
Lesion	2
Shearing	1
Skin Tear	8
DTI	1

These original wounds were tracked each week during the 12 weeks of the trial to record when wounds healed and how many were left at the conclusion. The number of wounds dropped every week of the trial down to a final number of 14 remaining.



The remaining wounds consisted of:

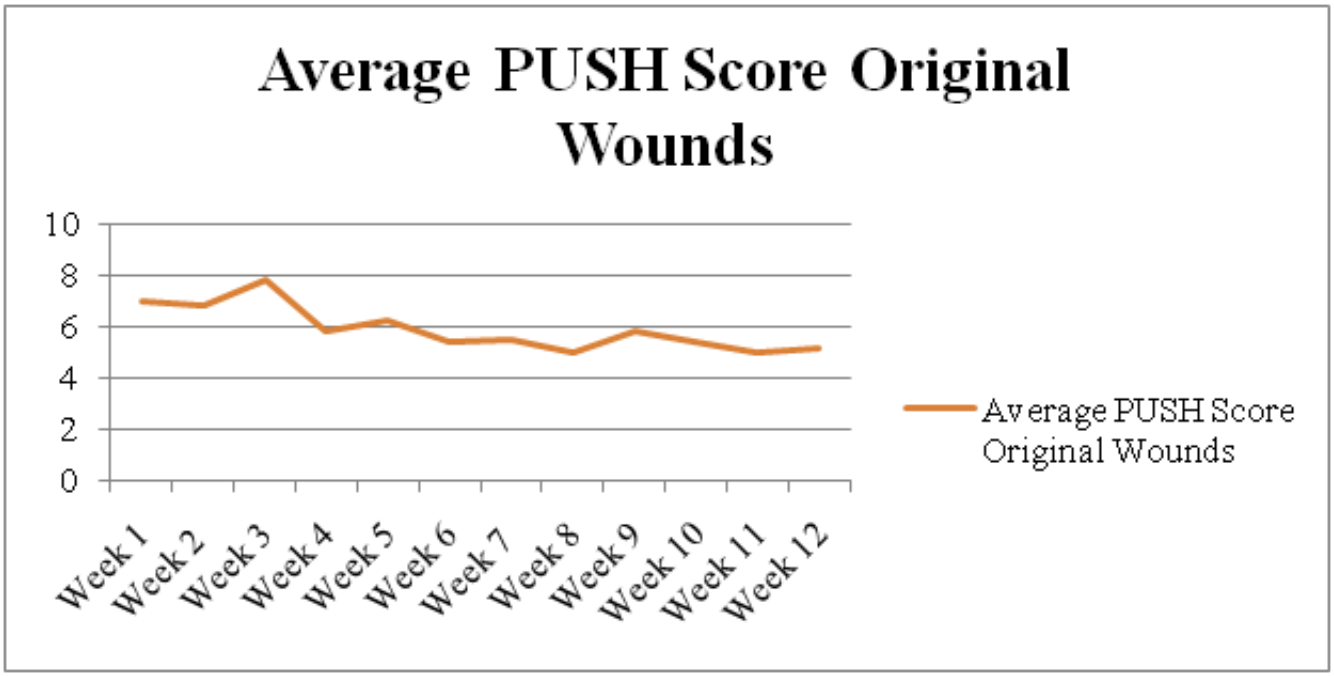
Type of Wounds	Total Wounds
Surgical	1
Stage 4	2
Stage 3	3
Stage 2	3
Stage 1	1
Unstageable	1
Venous Ulcer	0
Abrasion	0
Abscess	0
Blister	0
DTI	0
Edema	2
Lesion	0
Shearing	0
Skin Tear	1

Pressure Ulcer Score for Healing

Each week the Pressure Ulcer Score for Healing was done for each of the wounds in the trial and an average was taken to determine an overall score. The Pressure Ulcer Score for Healing looks at different parameters of a wound's weekly wound assessment and assigns them a score. This is totaled to find a score for each wound.

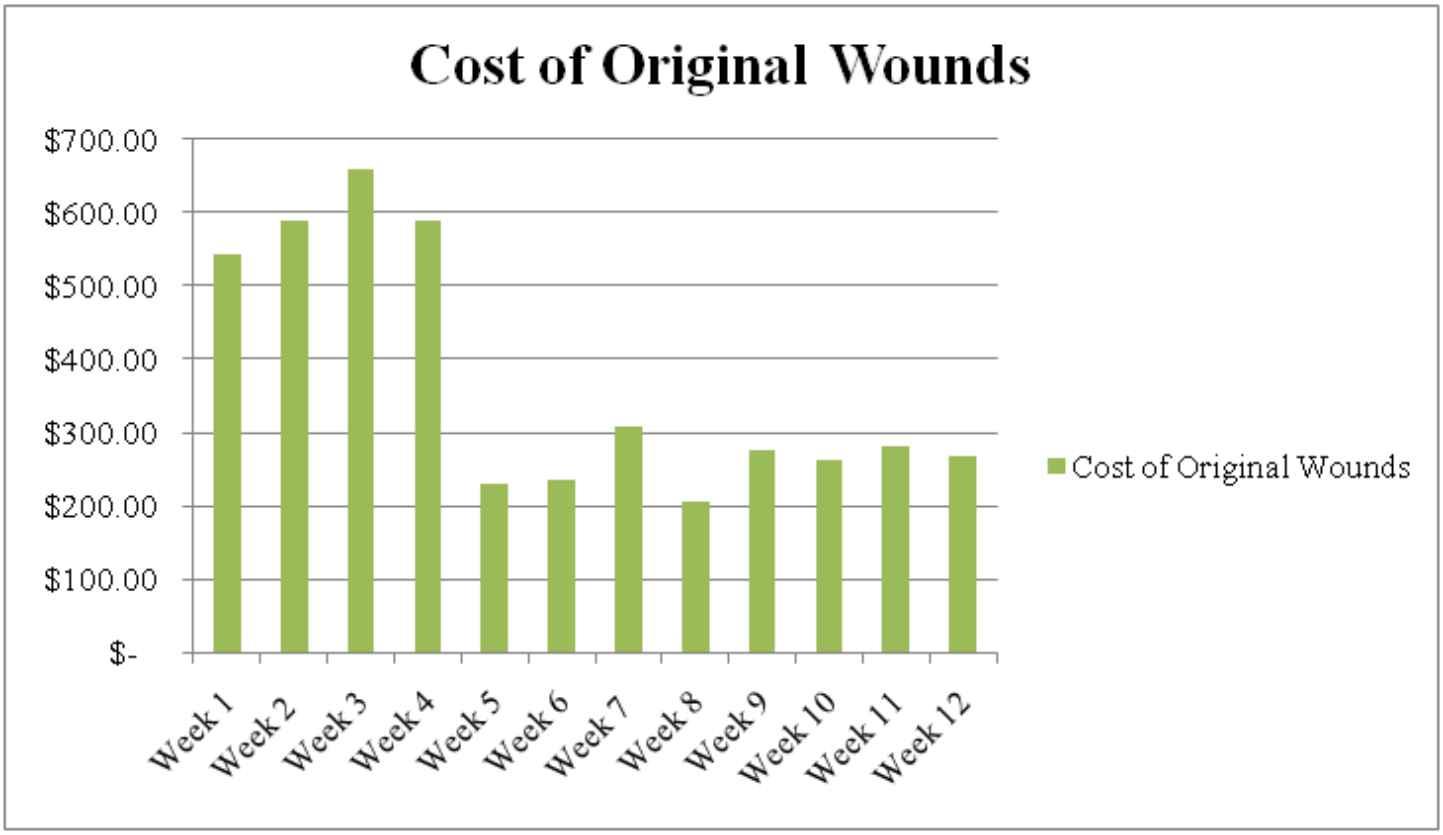
To score a wound, a number from 0-10 is assigned to the area of the wound (Length x Width). A score of 0 wound be a closed wound and a score of 10 wound be a wound with an area greater than 24 cm2. Then you assign a score of 0-3 on the exudate amount, 0 being none and 3 being heavy. Finally you assign a score of 0-4 to the wound bed tissue type, 0 for closed and 4 for necrotic. Once these scores are obtained, they are added together to find the overall Pressure Ulcer Score for Healing for that wound, 0 healed and 17 worst.

At the start of the trial the facilities average score was a 7. The number went down each week as we continued to track each of the 50 existing wounds to a final average score of 5.17.



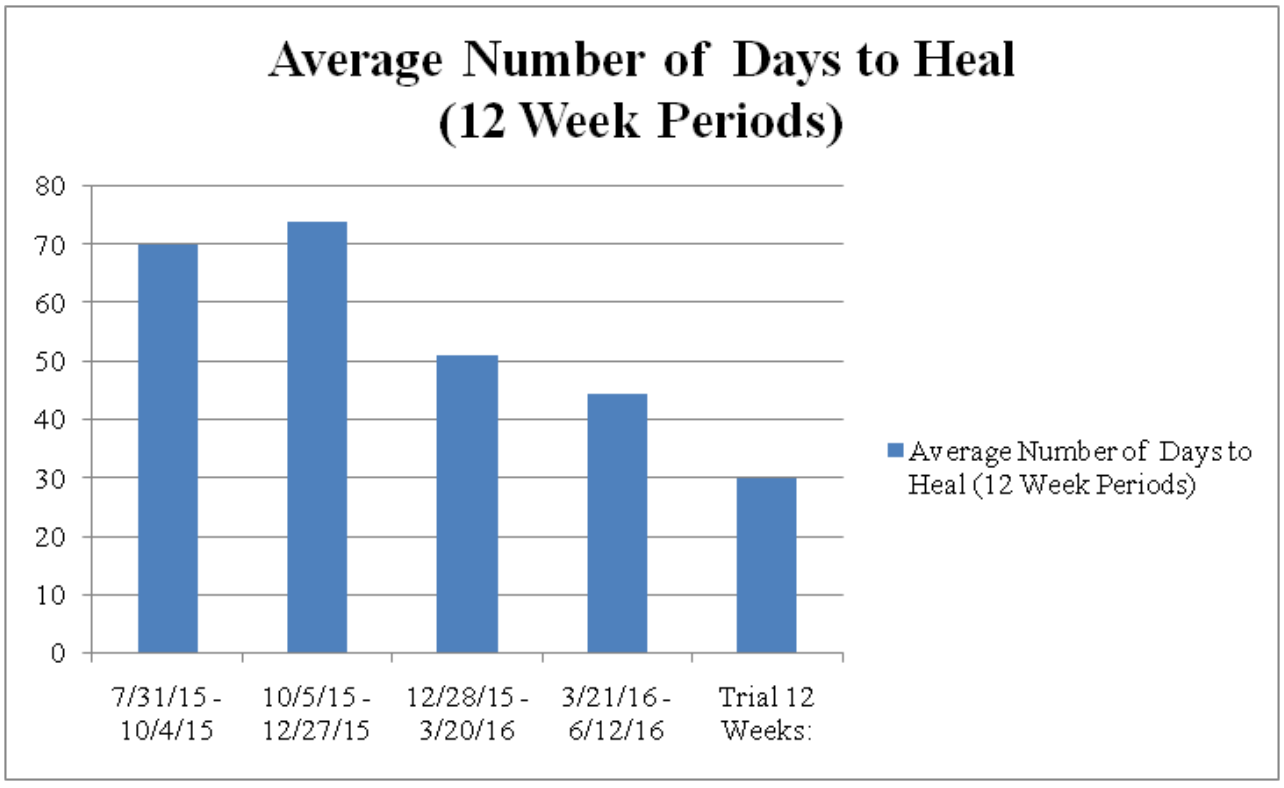
Cost of Dressings Ordered

We tracked the overall facility cost for wound dressings (for the 50 wounds) by looking at what was ordered each week. By totaling up the cost of each individual dressing used on each wound, we were able to track how spending changed during the 12 weeks. At the beginning of the trial the facility spent at total of $544.18 on its 50 wounds for 1 week. By week 12, the amount of money spent of the 50 wounds had dropped to a total of $268.14.



Average Wound Heal Times

During the course of the 12 week trial, we looked at heal times on wounds in the building and compared it to the prior 48 weeks. The average time to heal during the prior 48 weeks (broken out into 12 week periods) ranged from 74 days to 44 days. During the 12 week PUSH trial we observed an average wound heal time of 29.8 days.



Each week, the nursing staff at the test facility reported on their observations and the progress of the wounds in the study. Nursing consistently reported accelerated wound healing and healing in wounds that had been stalled. In one case, a foot that was a candidate for amputation (due to its severity) began to heal and was eventually closed and healed. Nursing also reported good patient compliance due to the small 2-3oz volume of each serving and good taste.

Conclusion

The findings of this study suggest that PUSH –derived dipeptide molecules with physiological functions act directly on skin cells. It has shown to genetically adjust the remodeling of damaged skin tissues during the process of wound healing. Patient compliance was excellent during our study due to minimal fluid requirements for ingestion and the light pineapple taste. PUSH (containing these dipetides) has shown to be effective to promote wound healing on stage 1, 2, 3, and 4 wounds sites. PUSH was also effective in promoting healing on stasis ulcers, diabetic wounds, deep tissue injury, surgical sites, unstageable wounds, and skin tears. By adding PUSH to our elderly resident diets, it improved moisture to the skin which allowed for better texture and a reduction of shearing.

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