

A Randomized Open Controlled Pilot Study of the Use of an Olivamine™ Based Nutritional Barrier* vs. a Balsam of Peru, Castor Oil and Trypsin (BCT)** based product in the Maintenance of Newly Epithelial Skin of Lower Extremity Ulcers

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BACKGROUND

Many patients who suffer from lower extremity ulceration successfully heal their wounds only to go on to experiencing re-ulceration at the original ulcer site.¹ Skin structures in a recently healed wound usually do not have the same strength and characteristics of mature skin. The importance of maintaining and promoting skin health and integrity cannot be over emphasized. Transepidermal water loss (TEWL) causes the stratum corneum layer of the skin to lose some of its protective properties leading to dehydration.² A good skin care regime is part of enhancing the skin's ability to maintain moisture and restore cells to normal health.

Recent changes to CMS no longer allow reimbursement Balsam of peru, Castor Oil, and Trypsin (BCT) based ointments with federal funds.⁸ While this product is prescribed for the treatment of ulcers it is widely used in the prevention of re-ulceration. Therefore, economical alternatives are necessary for patients with recently epithelialized ulcers. (average cost \$100/60g tube)

The Olivamine™ based nutritional barrier contains dimethicone which is reported to help prevent TEWL.³ Dimethicone is said to provide a semi-permeable barrier that protects the skin, does not slow down the recovery of the stratum corneum and allows for normal cellular respiration. (average cost \$9.86/4 fl. oz. tube)



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OBJECTIVE

The object of this randomized, open, controlled, pilot study is to determine the efficacy of Olivamine based barrier, an over the counter skin protective emollient, versus that of BCT ointment, a prescription only ointment. It is expected that the two products will be equivalent in their ability to retain moisture and improve healing by maintaining the integrity of the skin.

RESEARCH DESIGN AND METHODS

This randomized study compared the use of Olivamine based barrier to BCT ointment in two groups of patients. One group received Olivamine based barrier and the other group received BCT ointment.

Both groups were instructed to moisturize their lower extremity where their recently healed ulceration had occurred. A recently healed ulcer was defined as achieving complete epithelialization within 1 to 14 days prior to enrollment in the study. Patients were instructed to apply either the ointment, or cream, once a day or, in the case where their extremity was wrapped or bandaged, when their wraps or bandages were changed. Both groups were given a 6 week supply of the product. Randomization for the first patient was accomplished by a coin toss and subsequent patients were assigned to alternating groups.

Clinic staff evaluated the epithelialized ulcer area during regularly scheduled clinic visits. A photograph of the epithelialized ulcer area was taken at the first study visit and during regularly scheduled visits per standard clinical procedures.

PATIENT SELECTION CRITERIA

Inclusion Criteria:

Age: 35-80

Circulatory Status:

Ischemic or non-ischemic

Pulse may or may not be palpable manually. However, pulse must be audible on Doppler (if not palpable)

Neurological Status:

Charcot foot or No Charcot foot

Ulcer- recently epithelialized

Complete wound closure within 14 days

Exclusion Criteria:

Neurological Status:

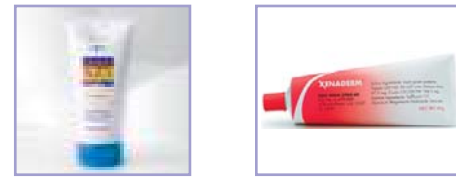
History of spinal or extremity nerve trauma

Severe alcoholism

Systematic Problems:

CHF or gout

PRODUCTS



PATIENT POPULATION DATA

	GENDER	AGE	
Male	45.5%	80+	0%
Female	54.5%	70-80	27.30%
	RACE	60-69	72.70%
Caucasian	100%	50-59	0%
Other	0		

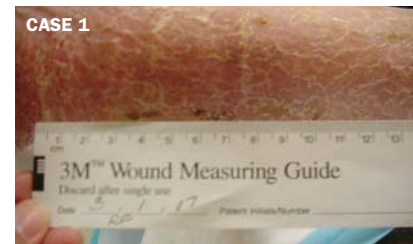
Venous	9.1%
Chronic Venous	18.2%
Diabetic	18.2%
Chronic Diabetic	18.2%
Arterial	0%
Chronic Arterial	36.4%

Patients w/History of Heart Disease	50%
Patients w/History of Rheumatoid Arthritis	37%

Patients w/ History of Advanced Wound Care Dressing Use	98%
Patients w/ History of Growth Factor Use	28%

Total # of Pts. Enrolled	# of Pts. Randomized to Olivamine	# of Pts. Randomized to BCT
20	10	10
Total # of Pts. Dropped out of study	# Olivamine Pts. Dropped out of study	# BCT Pts. Dropped out of study
8	5	3

RESULTS



Olivamine RF 3-1-07



Olivamine RF 3-20-07



Olivamine RF 4-17-07



Olivamine RF 4-24-07



BCT TS 3-26-07



BCT TS 4-2-07



Olivamine AP 3-26-07



Olivamine AP 4-24-07



BCT RD 3-20-07



BCT RD 3-27-07



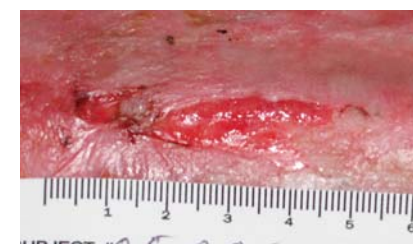
BCT RD 4-9-07



BCT CC 2-8-07



BCT CC 2-22-07



BCT CC 3-15-07 re-ulceration



BCT CC 4-10-07 re-ulceration

CONCLUSIONS

- No patients from the Olivamine based barrier arm of the study re-ulcerated.
- One patient from the BCT ointment arm of the study re-ulcerated.
- There were no statistical differences in the re-ulceration rate between the two study arms.
- 25% of patients had a self reported history of previous use of a preventive cream or ointment.
- 98% of patients had a history of previous ulceration.
- There were no clinical differences between the study arms regarding ease of application of the product.
- All patients in the study said that cost of ointment or cream would be a consideration in deciding on a product.
- 22 patients were enrolled in the study, 8 patients were dropped from the study for lack of compliance
- The most frequent reason given for non-compliance was forgetfulness.

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