

Report to Robert Ward, C.P.O. L.P.O for Presentation of
Adaptskin™ to the Veterans Administration
Pharmaceuticals & Therapeutics Review Board

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Prepared by:

Adapt Labs, Inc.

5780 Wimsey Lane

Bainbridge Island, Washington 98110

Ph: 888.842.2040, Fax: 206.201.6927

Web: www.adaptlabs.com, Email: info@adaptlabs.com

Introduction:

We are very pleased that the VA is considering making Adaptskin™ available to Veteran's with amputations and prosthetic devices. Adaptskin™ is a skin care product made specifically for protecting the residual limb at the socket skin interface.

While prosthetic technology has significantly advanced in the last ten years, the complications associated with the socket skin interface remain the same. Skin is an amazing organ, with its ability to protect, filter, regulate heat, and regenerate; however, its ability to adapt and stay healthy in a prosthetic socket environment is limited. As all amputees know, a prosthesis is especially prone to trapped moisture, friction, suction, uneven loading and stretching all of which leads to skin breakdown. Heat rash, abrasions, chafing, pressure soars, dry skin, blisters, boils, infected hair follicles, or a myriad of other residual limb irritations are caused as a result of this interface, simply because skin is not designed physiologically to withstand the environment inherent in wearing a prosthesis.

In conducting a review of published articles concerning skin break down in amputees, it was clear that amputees are faced with a unique skin care problem. Below is a brief summary of these findings:

- Koc, May 2008 – At least one skin challenge was detected in 105 of 142 individuals' studies for a rate of 73.9%.¹
- Meulenbelt, 2007 – A literature review of 56 references describing 76 cases concerning skin problems in lower limb amputees. The skin problem is specific to the amputation site and the use of a prosthesis. Most of the literature on this problem consists of case reports, and very little data on treatments.²
- Meulenbelt, May 2006 – The prevalence of skin problems in a series of 45 lower leg amputees of 65 years and older was 16%.³
- Dudek, April 2005 – Performed a 6 year retrospective chart review, and documented that 337 residual limbs (40.7%) had at least one skin problem. Dermatologic conditions are a frequent complication for the lower-extremity amputee who uses a prosthesis.⁴
- Dudek, May 2006 – A total of 528 skin problems were documented in 337 lower extremity residual limbs. Ulcers, irritations, inclusion cysts, calluses, and veracious hyperplasia were the five most common skin problems representing 79.5% of all documented skin disorders.⁵
- Hagberg, 2001 – Individuals with transfemoral amputation due to non-vascular causes were studied with mail survey to investigate prosthetic use and problems. 62% had skin sores or irritation from the socket.⁶
- Baars, June 2008 – 32% of amputees with normal hand function had skin problems and 70% of amputees who had impairment of their hand function had skin problems.⁷
- Lyons, March 2000 - This questionnaire-based, cross-sectional study of 210 amputees. Those with a skin problem were assessed by a dermatologist. A total of 34% of amputees experienced a skin problem. Lesions resulting from friction, pressure, and occlusion are common. Allergic contact dermatitis is seen in a third of patients with stump dermatitis. There are no features that distinguish allergic from irritant (chemical or physical) dermatitis.⁸

In short, it does not matter how much technology or craftsmanship goes into designing or fabricating the prosthesis, if there is a breakdown in the socket skin interface, then the prosthesis will not be worn and will serve little use. In the Atlas of Amputations and Limb Deficiencies, the American Academy of Orthopedic Surgeons states:

“Healthy skin on the residual limb is of the utmost importance to the successful use of a prosthesis. If the normal skin condition cannot be maintained despite the normal wear and tear the residual limb sustains, then the prosthesis cannot be worn, no matter how accurate the fit of the socket.”

Maintaining good skin health is critical to a patient’s mobility, independence, and life style.

Skin Care for the Amputee

As we have discussed, skin issues associated with limb loss has been recognized for decades, and over the years people have used a variety of products and home remedies to address this issue. Unfortunately, there are simply no published medical or scientific studies comparing the outcomes of these treatments, and a search of the published medical database did not reveal any controlled studies to address this very real issue. That leaves only antidotal evidence and testimonials of amputees and health care providers.

When considering a skin care product for an amputee it is vital that three distinct needs are met.

First, allow the skin to naturally hydrate itself. For many years, epidermal water content has been known to be crucial for skin plasticity and wound healing.⁹ Moisturization by inhibiting transepidermal water loss by occlusion hydrates the cells in the stratum corneum via water propagation from the deeper epidermal layers.

Second, assist the epidermis in its role as a barrier. A less glamorous role, but equally important, the skin acts as a vast waste disposal system riding the body of many toxic substances. For the amputee, these substances blend with acidic perspiration, rich with bacteria, and are trapped against the skin. This creates a poisonous brew that eats away at the stratum corneum, and breaks down the barrier function of the epidermis. To combat this, a moisturizing regime needs to have high occlusive properties while augmenting the lamellar lipid layers; thereby reinforcing the hydrophobic barrier of the epidermis, and keep the hazardous fluids away.

The third critical factor is to reduce the residual skin friction. Friction and shear loading removes cells prematurely from the stratum corneum severely compromising the epidermis. Typical moisturizers have little effect on the mechanical properties (i.e., distensibility, hysteresis, and elasticity) of the skin.¹⁰ When moisturizers are used to improve skin plasticity it is suggested that lipid-rich formulations be used.¹¹ Emollients, which are mainly lipids and oils, hydrate and improve the appearance of the skin by contributing to skin softness, enhanced flexibility, and smoothness. The "skin slip" or lubricity of some emollients aids in reducing the friction between the socket and skin. Higher viscosity emollients are especially important for transfemoral or other non-uniform weight bearing sockets.

Typical over the counter moisturizing lotions and creams can not meet the demanding needs of the amputee. The majority are lotions (oil-in-water emulsions) or creams (water-in-oil emulsions), that are easily washed away with perspiration. Others are chemically enhanced and can cause severe allergic reactions or can not be used on ulcerated or compromised skin. Low pH and sensory reactions, e.g., from lactic acid and urea, can cause burning on application and may reduce patient acceptance.

Other over the counter or prescription moisturizers use humectants. These chemicals (e.g. Urea, gelatin, Glycerin, etc.) are able to attract water from two sources: they enhance water absorption from the dermis into the epidermis, and in humid conditions they also help the stratum corneum to absorb water from the external environment. For the Amputee attraction of moisture is not the problem; typically there is too much moisture. High perspiration sealed in a warm stagnant environment surrounds every amputee's residual limb. A skin care product needs to repel this moisture not attract it.

A few over the counter products are marketed to amputees, but most of them only address limited specific aspects of the amputees needs. The most widely known product is AmpuBalm™, which is similar to other agricultural and or animal fat based products such as Bag Balm™, or Utter Butter™. Each of these consists primarily of mutton tallow, animal fats, and unrefined lanolin. While these products are based upon age old remedies, they possess a number of drawbacks and limitations for the amputee. These include but are limited to: known allergens, unpleasant odor, spoilage, and pesticides.

Silicone oils (EQ: Alps) consist of long carbon chain emollients that improve the appearance of the skin by contributing to skin softness, flexibility, and smoothness. The "skin slip" or lubricity of silicone oil aids in reducing friction, but by itself does not penetrate the epidermis and does not hydrate the stratum corneum. This is why it is typically found as an additive to other active ingredients in over the counter moisturizers.

Adaptskin™

Adaptskin™ is a hybrid of the best clinically proven emollients and occlusives, and is not considered a drug by the FDA. Therefore, the use of this product does not require a doctor's prescription.

Adaptskin™ blends clinically proven moisturizers and skin healing agents in a unique, non-water based formula that melts on contact, penetrates skin cell layers, and forms a waterproof barrier increasing hydration. In addition, Adaptskin reduces friction, and reinforces the skin's own natural defenses providing superior long term protection addressing the demanding needs of persons faced with limb loss. Adaptskin™ is Safe for all skin types, hypoallergenic, and contains no preservatives.

Petrolatum: Moisturizing emollient that has the ability to place a protective covering over the skin and penetrate the stratum corneum to aid in restoring skin health by reducing transepidermal water loss; thereby, allowing the skin to self hydrate. In addition, according to the current level of knowledge, the direct effects of petrolatum are not limited to occlusion. The hydrocarbon mixture intervenes directly in the lamellar lipid layers to produce its numerous positive effects.¹²

Medilan Ultra™: Ultra-purified hypoallergenic medical grade lanolin is an extraordinary natural emollient that closely matches human lipids and is able to imitate and augment many of the functions of human skin.

An important note should be made regarding lanolin and other animal fats. Unpurified lanolins and other animals fats found in other moisturizers have been documented to cause allergic contact dermatitis. Clinical trials have demonstrated that the medical grade lanolin used in AdaptSkin™ causes no allergic or irritant reactions, even in patients with severely compromised skin¹³. The medical grade lanolin used in AdaptSkin™ contains a maximum of 3% free lanolin alcohol. A free lanolin alcohol content of less than 3% is the determinant for a material's hypoallergenicity and for the product's suitability in the treatment of on hypersensitive patients. In addition, the ultra refined, medical grade lanolin used in AdaptSkin™ complies with the USP monograph for modified lanolin, which limits total pesticides to less than 3 ppm; additionally, no individual pesticide may exceed 1 ppm.

Beeswax: Used as an emulsifier for the active ingredients, and for its antiseptic properties. Beeswax also has occlusive properties aiding in the creation of a hydrophobic barrier.

Coconut Oil: Soothing emollient that also functions as a protective antioxidant.

Cyclomethicone: Cyclomethicone is a clear, odorless silicone with excellent spreading, easy rub-out, and lubrication properties. It leaves a silky-smooth feel when rubbed on the skin. Cyclomethicone evaporate quickly after helping to carry oils into the top layer of epidermis (Adaptskin 50™ only).

Lemon Oil: Natural citrus oil used for fragrance and antioxidant properties.

One reason why AdaptSkin™ is so effective as a moisturizing emollient is that it possesses a number of both chemical and physical similarities to human stratum corneum lipids. These similarities are listed below:

Chemical Similarities

Cholesterol, lanosterol and other wax esters
 Cholesterol and other sterols
 Free and esterified fatty acids
 Hydrocarbons

Physical Similarities

Solid – liquid phase at skin temperature
 Liquid crystalline structures
 Multi-lamella vesicle formation
 Partially occlusive film formation

Adaptskin™ has been tested and widely used by Amputees for over 5 years with the majority of sales coming via word of mouth and product performance. As a grass-roots company we have received nothing but positive feedback from distributors, practitioners, and most importantly from amputees themselves. In the appendix you will find a few of the testimonials we have received over the years. In addition, you can see amputees chatting on the Heather Mills-Amputee Forum (www.heathermills.eu/forum/) about the benefits or Adaptskin™ and how it has help them.

Questions:

1. How many Veterans Would be Candidates to use Adaptskin™?

Any amputee in the VA system should be considered a candidate for the use of Adaptskin™. Amputees will have skin problems. Maintaining good skin health is critical to a patient's mobility, independence, and life style. While Adaptskin™ is an excellent treatment for skin breakdown, it is primarily designed to be part of a preventative skin treatment regime.

An amputee who conducts a daily hygiene and skin care maintenance program will see far fewer skin breakdown issues and will have less need of VA services.

Number of Veterans with amputation:

Based upon the numbers we could gather, there are approximately 6,000 new amputations performed within the VA per year. The lifespan is quite variable as younger 20 year old will live 60 years, but a geriatric individual with diabetes and vascular disease, which make up the largest number might only have 3 to 5 years remaining. Using a median lifespan for a veteran of 25 years, the VA supports approximately 150,000 veterans with limb loss.

In 2000, it was estimated that there were 26 million veterans, and currently there are 304 million in the USA, and 1.7 million individuals in the USA with amputations (Amputee coalition of America fact sheet). Therefore one can estimate that -- If 1.7 million amputees out of total USA population of 304 million, then the number of veterans would be at least $1.7 \text{ million} * 26 \text{ million} / 304 \text{ million} = 145,000$ veterans with limb loss.

According to a February 2008 DOD report, major amputations represent 2.3% of the 31,289 U.S. troops wounded in action in Operation Iraqi Freedom and Operation Enduring Freedom¹⁴. Today there have been approximately 30,182 US troops wounded in Iraq and 2,257 in Afghanistan¹⁵. This would indicate that there are approximately 756 new major amputees from the current conflicts that should expect up to 40 years or 275,085 days in one or more prosthesis.

2. Cost effectiveness of Adaptskin™. Typically patents are getting anywhere from 3 to 6 months per 4oz jar of Adaptskin™. At a cost to the VA of \$12.50 per 4oz. or \$3.13

per ounce, an amputee who only gets minimal coverage of 3 months, the cost would equate to 14¢ per day. If you were to consider one of the recently wounded veterans from Iraq or Afghanistan who will live an additional 40 years with a prosthesis, and maintains a daily skin care ritual that includes Adaptskin™. The cost to the VA would be approximately \$50 per year, or cumulatively \$2000.

The cost of a daily skin care regime that includes Adaptskin™ is minimal when considering the costs associated with the treatment and support of an amputee who has skin breakdown, or worse can not wear their prosthesis and is no longer independent and active. For example, assume a veteran with a transtibial amputation develops a blister on their distal end: office visit to correct this problem (estimated, \$120 for each visit), assuming it escalates into requiring a course of antibiotics (approximately \$50 to \$500), finally revision surgery is necessary (approximately \$5,000 to \$25,000). While these are estimated costs, and do not address the additional costs that could be incurred (i.e. additional wheel chairs, crutches, assisted living...etc.). Clearly, preventative care is the most cost effective approach.

There is enormous value in assisting a veteran in regaining at least a percentage of their previous mobility and independence. This is evident in the approximately \$50K+ spent in fitting and training a new amputee to walk. The cost spent on preventative care and Adaptskin™ will go a long way in promoting the prosthesis use and the amputee's active life style.

3. What's the difference between the 50 and the 90?

Adaptskin 50™: Medium viscosity for more general applications and daily use. Adaptskin 50™ uses cyclomethicone to enhance the skin's barrier protection and leave a lighter, silky-smooth feel when applied.

Adaptskin 90™: Thicker, more concentrated product for areas of localized skin damage/irritation or areas of high abrasion and stress. Adaptskin 90™ is a lipid-rich formulation providing extended topical coverage and protection.

Some amputees use both Adaptskin™ 50 and 90, however, in conversations with many we find that they generally prefer using one viscosity over the other. It comes down to personal preference and feel, and can vary based on the type of prosthesis they wear, area of the country they live, and their activity level.

4. Safety of Adaptskin™:

First and foremost, Adaptskin™ has been used daily by amputees for the last five years and was widely tested prior to being introduced to the market. There has never been any reported, rumored, or suspected case of Adaptskin™ causing patient harm or irritation of any kind.

All ingredients used in making Adaptskin™ have been extensively clinically tested or recognized as FDA safe for cosmetic use. In addition, individual testing of the active ingredients has demonstrated their safety and effectiveness. Findings from a few of the clinical studies supporting this includes:

- White petrolatum appears to be a safe and a much less costly alternative to bacitracin ointment. There seems to be no significant increase in wound infections with petrolatum, and the risk of allergic contact dermatitis is eliminated.¹⁶
- The outstanding safety of Ultra-purified medical grade lanolin (Medilan) has been demonstrated in a number of clinical patch test studies:
 - In the first study, carried out in four European hospitals on 149 lanolin sensitive patients*, only one positive reaction (1/149) to MEDILAN was observed. It is worthy of note that the one positive reaction was among Wycombe Hospital group of patients where most of the patients taking part in the study were from the leg-ulcer clinic where the incidence of lanolin sensitivity is believed to be high^{17 18}.
 - Ippen found no positive reactions when patch testing 40 lanolin sensitive patients with MEDILAN¹⁷.
 - In a 9-month study carried out at Bristol Royal Infirmary on 221 dermatological patients, 13 (5.9%) were found to be lanolin sensitive yet none of them (0/13) reacted to MEDILAN itself¹⁹.

* For the general public, typically only 1 in 10,000 is found to be lanolin sensitive.

Appendix A - Testimonials

What amputees across the country are saying about Adaptskin™!

"I've tried everything out there to protect my skin while I'm wearing my prosthesis. Some creams smell bad, some of the other stuff you can't get off, and others just seem to disappear. Bottom Line is: Adaptskin™ works! It stays on, doesn't become odorless, and protects my skin. When I don't use it, I know, as I notice tender and irritated areas right away."

– Nick Sikeo (Florida)

"I have been an amputee for more than 40 years and have been very active in sports over the years. Having tried every remedy, potion, lotion, and trick imaginable (both commercial and homemade) when a hot spot occurs, nothing comes close to your product. You have revolutionized skin care for amputees. I will go so far as to say that any prosthetist not recommending this to their patients is doing them a great disservice."

– Jim Houser (Tennessee)

"I received a sample of Adaptskin™ at the ACA conference in Atlanta back in June. I finally started using the sample you gave me and just want to say thank you for a great product!"

– Martha Adams (Georgia)

"I have been an amputee for a little over 3 years, and I have used a lot of products to keep my leg moisturized and repel sweat during the day and nothing worked. I live in Arizona where, as you know, it is very HOT, and everything I have used just didn't cut it. I started using Adaptskin™ about 6 months ago, and ever since my limb has been very healthy. The best thing about the Adaptskin™ product is that it repels the sweat from my limb. In Arizona it gets so hot here, after 5 minutes of activities outside you start to sweat. I have been able to start to do things that I never thought I would be able to do. For instance, I'm able to coach my kid's football team this year. I don't have to worry about any discomfort in my leg due to the skin breaking down from moisture. I would have to say that you guys have done a great service for amputees in developing Adaptskin™."

– Joe Newlon (Arizona)

"I use a vacuum system prosthesis and over the years I've had a variety of skin problems on my stump. Since I started using Adaptskin™ everyday I haven't had any problems with skin breakdown."

– Pat Lott (Ohio)

"I have used Adaptskin™ twice a day and my leg has looked or felt better. I am ordering my second jar as nothing I have ever tried before works like Adaptskin™. It is a superior product."

– Herbert Simonson (Pennsylvania)

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