Resolution of Early Stage Pressure Sores after treatment with Specific Skin Cream: A Prospective, Comparative Study

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Abstract

Pressure ulcers are common among selected patient populations. Early therapeutic intervention may result in a decrease in the number of ulcers that progress to a later stage. The efficacy of specific skin creams for the treatment and prevention of early stage pressure ulcers has not previously been evaluated. We compared the healing rates of paired, early stage pressure ulcers treated with either Curaderm hp cream, Eucerin cream, or Sween cream. Those ulcers treated with the Curaderm hp cream demonstrated a 100% cure rate within 14 days. The ulcers treated with either the Eucerin cream or Sween cream had a variable outcome. Some of the ulcers were partially healed while others did not heal or progressed to a later stage. The data suggests that the early use of specific skin creams may be useful as adjunctive therapy in the overall treatment protocol of early stage pressure ulcers.

Introduction

The prevalence of pressure ulcers in the elderly has been estimated to be between 3 – 11% (1 – 3). The morbidity and mortality associated with pressure ulcers is significant. The death rate in those with pressure ulcers may be four-fold greater than in those without pressure ulcers (4). In addition, septic, elderly patients with pressure ulcers have a hospital mortality rate in excess of 50 percent (5 – 7). Theoretically, pressure ulcers are preventable (8). However, even with the best care, pressure ulcers may still occur. When they occur, the treatment of pressure ulcers can be expensive (7, 9). This cost includes intensive nursing care (10 – 12) as well as adjunctive therapies such as anti-pressure devices (13), protective dressings, and skin treatments (14, 15).

Resolution of pressure ulcers is dependent upon several factors: the reepithialization of the ulcer (15, 16); optimization of the nutritional status (17, 18); and a decrease in the shear forces on the skin (8, 19, 20). In the infirm elderly, a major factor in the formation of pressure ulcers is a decreased ability of aged skin to withstand sheer forces. Notable changes in the skin of the elderly include a decrease in the number of dermal blood vessels and alterations in the way collagen is organized and deposited (21, 22). These changes may result in a decrease in the number and strength of the epidermal-dermal ridges, making such skin more susceptible to injury (21, 22).

A reduction of local sheer forces may limit the incidence and progression of early stage pressure ulcers. The use of skin creams has been postulated to aid in the reduction of sheer forces (15). However, to date, there have been no clinical trials comparing the effectiveness of various skin creams for the treatment of early stage pressure ulcers. We noted previously that a specific skin cream containing the Curaderm hp (PhytaTek Laboratories, Inc. Santee, CA) was very effective in the treatment of mild eczema (Massey PM and Malkinson FM, data not published). The elderly patients who used this skin cream also appeared to have an accelerated rate of healing of early stage pressure ulcers. We postulated that the ulcer resolution might be secondary to the lubricating effects of glycerin-based skin creams. To evaluate the efficacy of various skin creams as an adjunctive therapy for early pressure ulcers, we directly compared the healing rates of early stage pressure ulcers treated with treatment product of the invention versus matched pressure ulcers with either Eucerin or Sween cream.

Patients and Methods

This protocol was reviewed and approved by the Human Investigation Committee of Rush-Presbyterian St. Luke's Medical Center.

Ten patients with bilateral early stage ulcers were evaluated and considered for enrollment into the study. All patients were located in the geriatric medical ward of the Johnson R. Bowman Center, Rush-Presbyterian St. Luke's Medical Center, Chicago, Illinois. The requirements for enrollment included bilateral pressure ulcers at the same stage of development. The ulcers had to be at opposite but identical sides of the body (e.g. bilateral heels, bilateral hip trocanters). Only stage one and stage two ulcers were considered in this study. Stage one pressure ulcers were defined as a blanchable, erythematous patch that is warm and painful (23). Stage two pressure ulcers were defined as non-blanchable, erythematous and eroding into the epidermal layers. In addition, there may be a surrounding area of scaling and erythema (23). The excision criteria were the following: albumen less than 2.0, topical steroid, topical antibiotic, or topical emollient use in the ulcer region for at least two weeks prior. Patients were randomly assigned to one of two groups: Group A; patients treated with the Curaderm hp cream (PhytaTek Laboratories, Inc., Santee, CA) and Eucerin cream (Beiersdorf, Inc., Norwalk, CT), or Group B; Patients treated with the Curaderm hp and Sween cream (Sween Corp., Lake Crystal, MN). Five patients used the Curaderm hp/Sween cream combination and five patients used the Curaderm hp/Eucerin cream combination. The creams were applied in the following manner: The Curaderm cream was applied to one ulcer (randomly chosen) and either Eucerin (Group A) or Sween cream (Group B) was applied to the paired ulcer, once a day, in the morning by the ward nurses. The amount of cream applied varied per the size of the ulcer. Nurses were instructed to apply an even layer of all creams to the ulcer bed and not to vigorously rub it in. Ulcers were evaluated every other day. There were no additional changes in the nursing protocol except for the morning application of the test creams.

The skin creams have the following compositions:

Curaderm hp cream: Purified water, aloe oil, vegetable glycerin, cetyl alcohol, steareth-20, PEG 150-sterate, polysorbate 60, sodium PCA, aloe vera, almond meal, mugwort, guar tripropyltrimonium chloride, quaternium 15, methylparaben, propylparaben, potassium sorbate, natural fragrance, vitamins A, E & C.

Eucerin cream: water, mineral oil, isopropyl myristate, polyethylene glycol-40, sorbitan glycol, cetyl palmitate, magnesium sulfate, aluminum state, lanolin alcohol, BHT, methylchloroisothiazolinone-methlyiso-thiazolinone.

Sween cream: water, lanolin alcohol, cetyl alcohol, glycerin, ichthyo liver oil, (natural vitamins A and D), sodium lauryl sulfate, beeswax, xanthan gum, fragrance, quaternium 15, methylbenzethonium chloride, BHT.

The ulcer dimensions were measured at the greatest diameter and then at 90 degrees to that axis. The area was then calculated as the length times the width. The % area healed was calculated as follows: (original ulcer area – new ulcer area/original ulcer area) x 100% (24, 25). The ulcer area was measured every other day. The ulcer treatments could not be completely blinded because of the unique physical characteristics of the individual creams. The nutritional status of each patient was evaluated per the serum albumen, protein, and the cholesterol. In addition, the renal function was followed per the blood area nitrogen and creatinine. The hemoglobin was also recorded.

Table 1

Patient Demographics and Admission Serum Laboratory Values (a)		
	Group A **(b)**	Group B **(c)**
Age	69 +/- 4	68 +/- 3
Male/Female	1/4	0/5
Serum albumen, g/dl	2.9 +/- 0.5	2.9 +/- 0.4
Cholesterol, mg/dl	165 +/- 79	172 +/- 92
Hemoglobin, g/dl	11.2 +/- 3.5	12.1 +/- 3.1
Urea nitrogen, mg/dl	27.6 +/- 15	28.8 +/- 20
Creatinine, mg/dl	1.7 +/- 1.3	0.9 +/- 0.3
Glucose, mg/dl	183 +/- 58	146 +/- 50

(a) Results are given as mean +/- SD.
(b) Patients treated with Curaderm hp and Eucerin creams.
(c) Patients treated with Curaderm hp and Sween creams.

Table 2

Admission Diagnosis, and Location and Stage of Test Ulcers			
		ULCER	
Patient	Diagnosis	Ulcer Stage	Location **(a)**
Group A **(b)**			
1	Pneumonia/CA **(c)**	II	elbow
2	Sepsis	I	heel
3	Stroke/PD **(d)**	II	heel
4	Renal failure	I	heel
5	Pneumonia	II	Medial maleoius
Group B **(e)**			
1	Dehydration/CA	II	Lateral foot
2	CLL **(f)** /Anemia	I	Lateral maleoius
3	Dehydration/DM **(g)**	II	Anterior tibis
4	Urosepsis	II	Buttock
5	Urosepsis	I	heel

(a) Bilateral location of stage-matched ulcers.
(b) Curaderm hp and Eucerin cream treated group.
(c) Metastatic cancer, unknown primary.
(d) Parkinson's disease.
(e) Curaderm hp and Sween cream treated group.
(f) Chronic lymphocytic leukemia.
(g) Diabetes mellitus.

Table 3

Initial Ulcer Area		
Group A	Ulcer Area **(a)**	
Patient	**Curaderm hp treated**	**Eucerin treated**
1	4.0	3.8
2	2.8	3.0
3	4.2	3.6
4	2.7	2.7
5	3.1	3.2
Group B		
Patient	**Curaderm hp treated**	**Sween treated**
1	5.5	5.7
2	2.7	2.0
3	4.5	3.6
4	4.6	5.0
5	4.8	4.6

(a) Initial area (cm^2) measured per Methods.

Results

Ten patients were accepted into this study. The majority of the patients were female since the majority of patients admitted to the Johnson R. Bowman Center at the time were female. The patients were all over 65 years of age. They were uniformly nutritionally compromised as measured by the serum albumen and cholesterol (TABLE 1). Their nutritional status did not improve significantly over the time of the study although adequate nutritional intake was provided. Most patients were anemic and several had some compromise of their renal function (TABLE 1).

Participants with matched ulcers were of similar stage and area (TABLE 2 and TABLE 3) and were randomly divided into two groups. Patients in GROUP A were treated with Curaderm hp and Eucerin cream, whereas those patients in GROUP B were treated with Curaderm hp and Sween creams. In addition, the ulcer treated with Curaderm hp was also randomly chosen. In both groups three patients had bilateral stage II pressure ulcers and two patients had bilateral stage I pressure ulcers (TABLE 2). All patients had significant underlying disease (TABLE 2). One patient died soon after the conclusion of the study (GROUP A, patient #1). Only one patient was ambulatory but with assistance (GROUP B, patient #4).

The rates of healing of the pressure ulcers are represented as the % area of the wound healed over time (FIGURE 1, Curaderm hp and Eucerin and FIGURE 2, Curaderm hp and Sween). In GROUPS A and B, all ulcers treated with the Curaderm hp demonstrated complete healing within 10 days. The healing rate of these ulcers was not dependent upon the stage or location of the ulcer. In addition, the area surrounding the ulcers often was eczematous. After 3 – 4 days of treatment with the Curaderm hp the eczema resolved.

The ulcers treated with Eucerin cream demonstrated an average improvement of 20 – 30% after 10 days as measured by the % area healed (FIGURE 1, Graphs of 5 patients comparing the % healing of the Curaderm hp cream versus Eucerin cream on each patient). In addition, the local, eczema surrounding the ulcers was not relieved completely by treatment with the Eucerin cream.

The pressure ulcers treated with Sween cream (Figure 2, Graphs of 5 patients comparing the % healing of the Curaderm hp cream versus Sween cream on each patient), did not demonstrate a healing rate significantly different from those treated with Eucerin cream (Figure 1). However, one ulcer (patient #3, stage II) treated with Sween cream did progress to a stage III ulcer and required additional medical therapy.

Comment

This study was undertaken to evaluate the role of a specific skin cream alleged to have efficacy in the treatment of early stage pressure ulcers. We directly compared the healing rates of matched, early stage pressure ulcers treated with different skin creams (Eucerin, Sween and Curaderm hp creams).

The patient population in this study reflected, in general, the nursing home population admitted to our hospital during the study interval. All patients were compromised and had severe underlying disease (Tables 1 and 2). Most were immobile and had some compromise of their mentation. These patients represent a population that is profoundly susceptible to the development and progression of pressure ulcers. In this population any therapy that prevents the breakdown of skin may impact positively on the incidence and progression of pressure ulcers. Our data suggests that the use of a specific skin cream may promote the healing of pressure ulcers. All early stage pressure ulcers treated once a day with the Curaderm hp cream completely resolved within a ten-day period (Figures1 and 2). The matched pressure ulcers treated with either Eucerin or Sween creams demonstrated a moderate improvement, no improvement or a progression to a later stage ulcer (Figures1 and 2).

It is unlikely that the observed healing rates in the Curaderm hp treated ulcers were due to chance alone. Although the study population was small, many variables were eliminated because the test creams were directly compared on the same patient. Patients with matched ulcers were randomized to either treatment protocols. In addition, the ulcers treated with the Curaderm hp were randomly chosen. However, it was not possible to adequately blind the investigators as to which ulcer received which cream. The physical characteristics of each cream (odor, color, texture) were sufficiently different that the investigators could tell which ulcer was being treated with the Curaderm hp even if the creams had been applied several hours earlier. In addition, the fragrance of the Curaderm hp was so distinctive, that only vigorous washing of the ulcer area would remove the odor. Vigorous washing of the ulcers was not allowed in this study (see Methods).

The use of skin creams could, theoretically, reduce the friction and sheer forces to which the skin is subjected. Sheer forces and friction have been shown to be major factors in the development and progression of pressure ulcers (1, 9). Reduction of sheer forces through the use of skin creams may slow, and possibly reverse the progression of some ulcers (8, 19, 20). Until now, however, there are no controlled studies evaluating the efficacy of skin creams for the treatment of early stage pressure ulcers. Our data demonstrated that the use of a specific skin cream may be beneficial in the overall treatment of early stage pressure ulcers

Specific skin creams may make skin more supple and less dry. This may aid in relieving some of the friction and sheer forces their skin is subjected to while in bed. A reduction in the sheer forces and friction may aid the healing of pressure ulcers. However, the Curaderm hp-treated pressure ulcers totally resolved, whereas those treated with Eucerin and Sween creams did not. It is not likely that there are major differences between moisturizing properties of the tested creams since all three are glycerin-based. Therefore, some component of the Curaderm hp formulation might very well promote the healing of damaged skin.

This data demonstrates that the use of a specific skin cream will promote healing of early stage pressure ulcers. However, it is unlikely that any single agent will supplant the role of nursing care in the treatment of skin breakdown. However, the use of Curaderm hp cream appears to promote ulcer resolution and therefore its use, as part of an aggressive medical protocol, may favorably impact on the economics of pressure ulcer therapy (9, 15, 18).

Figure 1
Patient #1
(CC = Curaderm hp; EC = Eucerin)

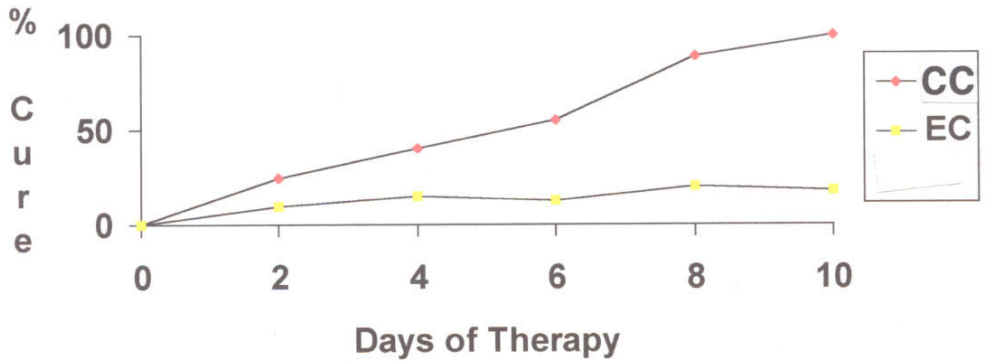


Figure 1
Patient #2
(CC = Curaderm hp; EC = Eucerin)

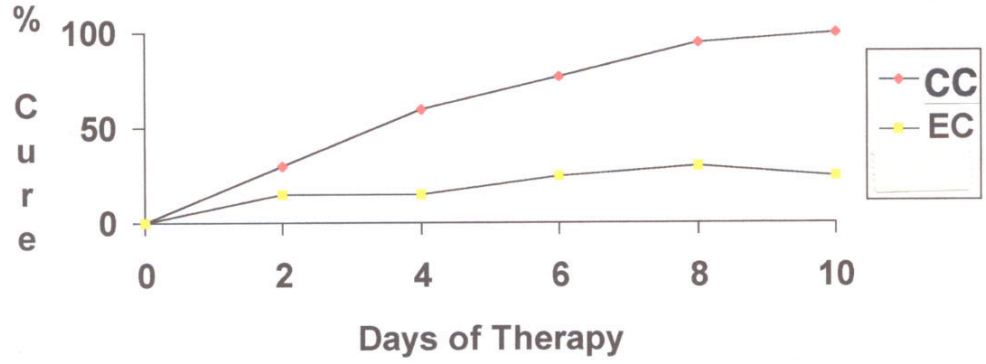


Figure 1
Patient #3
(CC = Curaderm hp; EC = Eucerin)

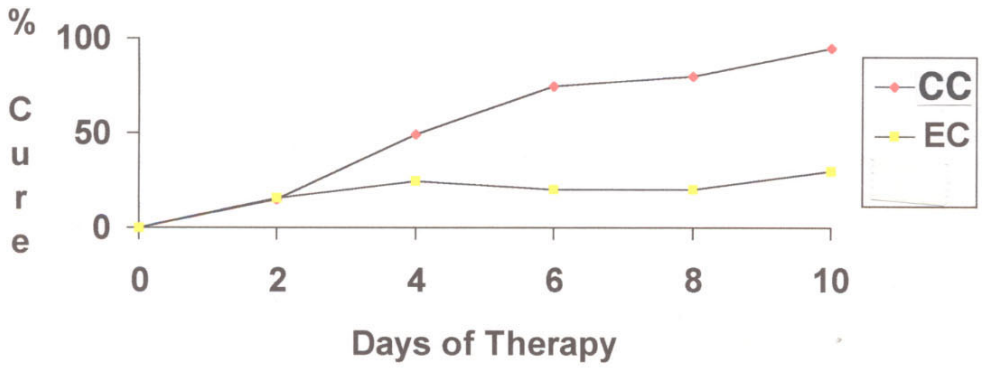


Figure 1
Patient #4
(CC = Curaderm hp; EC = Eucerin)

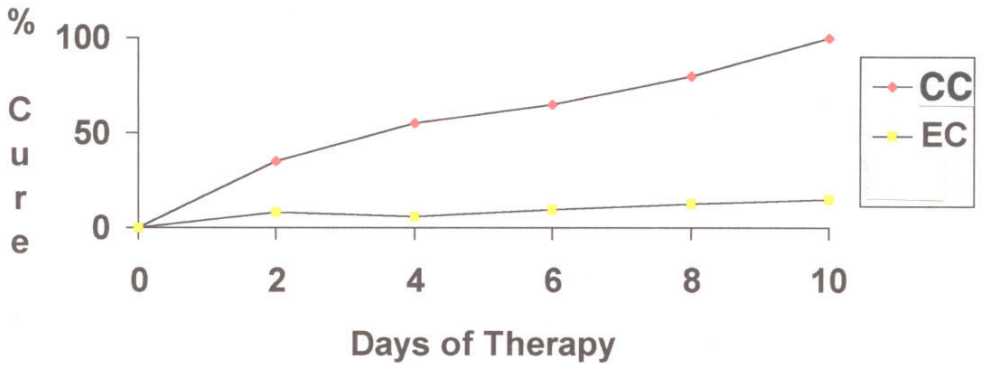


Figure 1
Patient #5
(CC = Curaderm hp; EC = Eucerin)

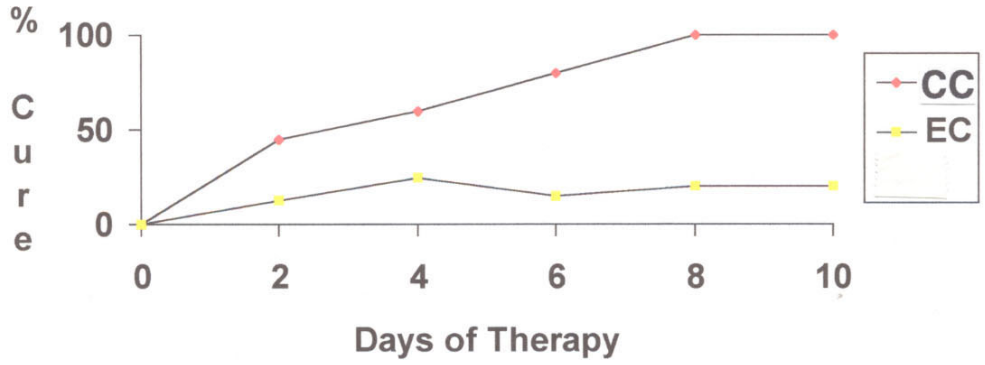


Figure 2
Patient #1
(CC = Curaderm hp; SW = Sween)

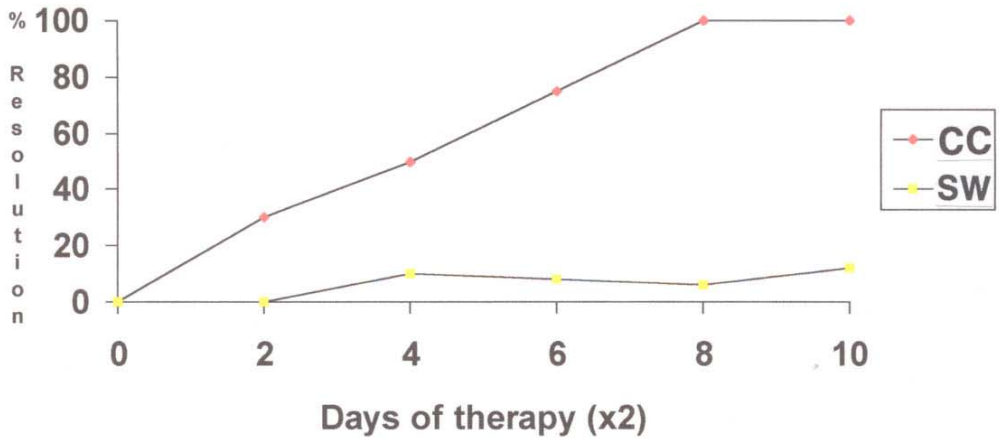


Figure 2
Patient #2
(CC = Curaderm hp; SW = Sween)

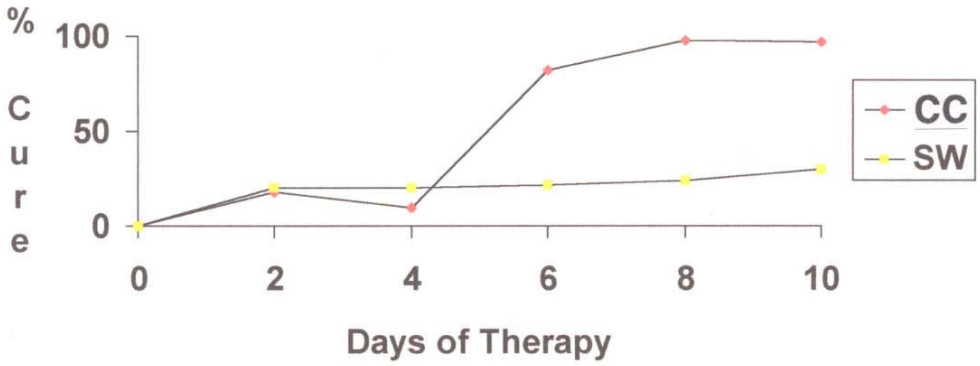


Figure 2
Patient # 3
(CC = Curaderm hp; SW = Sween)

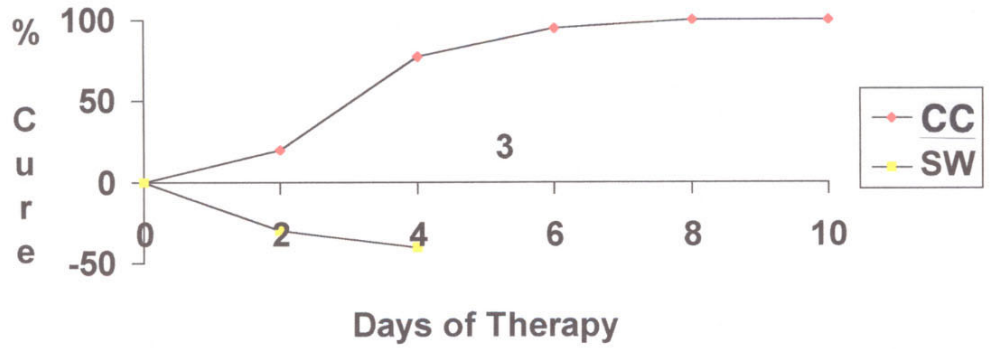


Figure 2
Patient #4
(CC = Curaderm hp; SW = Sween)

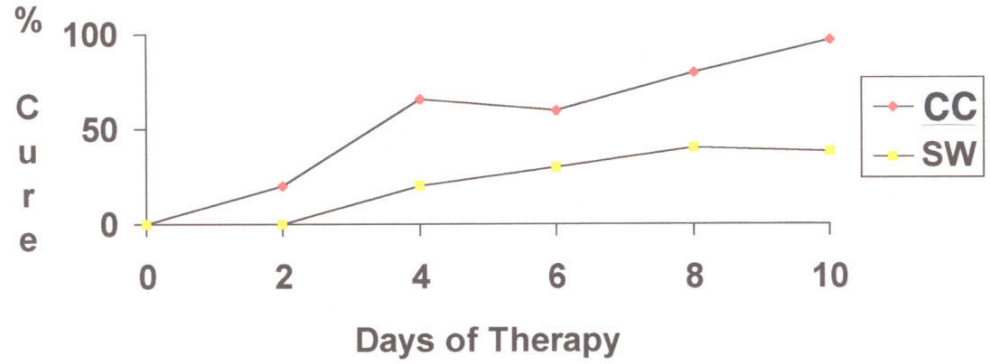
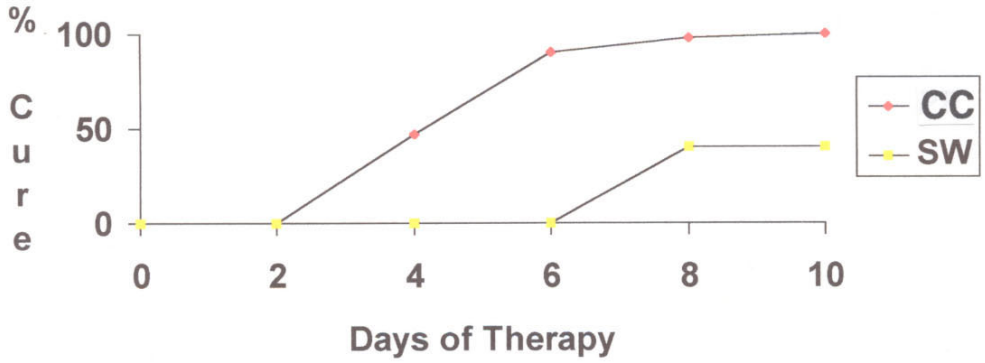


Figure 2
Patient #5

(CC = Curaderm hp; SW = Sween)



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