

484

WOUND HEALING ASSAY

IVY RESEARCH PROTOCOL: #3791

CONDUCTED: October 23, 1978 to  
December 18, 1978

OBJECTIVE:

To determine whether the materials tested interfere or enhance the healing process of superficial dermal wounds.

SUBJECTS:

Four subjects (4) completed the experiment.

METHOD:

Seven (7) blisters were induced on the volar forearms of four (4) adult, white males using the ammonium hydroxide blister technique by Frosch and Kligman - Brit. J. Derml. Vol. 96, pp. 461-473, 1977.

Immediately following the removal of the blister roofs, the wounds are treated with either (1) Aloe Vera Extract (2) Aloe Vera Extract with Quinone (3) Aloe Vera Butter Body Cream (4) Aloe Vera Butter Body Cream with Quinone (5) Aloe Vera Butter Body Cream Base (6) a non-treated non-covered control (7) Telfa covered wound.

The wounds were treated and covered with the appropriate test material then covered with a Telfa dressing and permeable Micropore Tape and this dressing was changed every 48 hours.

Wound healing was evaluated during treatment at 24 hours, and every 48 hours thereafter for a period of two weeks with a follow-up examination at three weeks.

The wounds were evaluated with the aid of a Zeiss Stereo Microscope under magnification of 6-40X's.

The grading system was as follows:

ERYTHEMA

- 0 = none
- 1 = mild
- 2 = moderate
- 3 = severe

WOUND HEALING ASSAY

RE-EPITHELIALIZATION:

Percentage of entire wound surface

DERMATOGLYPHICS: (Skin markings)

- 0 = no skin markings visible
- 1 = major lines beginning at the wounds' surface
- 2 = major lines 50% of the entire wound surface
- 3 = major lines entire wound surface
- 4 = major lines throughout with minor lines beginning
- 5 = major and minor lines throughout

N.B. The grading for Dermatoglyphics will not begin until the wound is 100% re-epithelialized.

WOUND DEPRESSION

The depth of the wound as examined through the Stereo Microscope

- 0 = no depression at all - wound surface even with surrounding skin
- 1 = 75% filled in
- 2 = 50% filled in
- 3 = 25% filled in or less

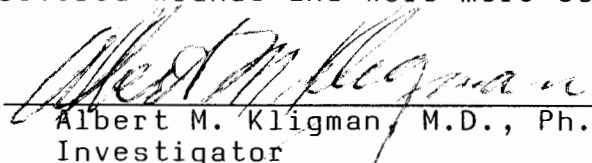
RESULTS:

Individual subject data is found in the enclosed Tables.

CONCLUSIONS:

It is our opinion that the Aloe Vera materials tested did not interfere with the normal rate of superficial dermal wound re-epithelialization nor did they enhance the process any faster than the covered non-treated control wounds at the end of three weeks.

It can be stated that the wounds treated with Aloe Vera healed better than uncovered wounds and were more cosmetically gratifying.

  
\_\_\_\_\_  
Albert M. Kligman, M.D., Ph.D.  
Investigator

IVY RESEARCH LABORATORIES, INC.  
SUITE 226-3401 MARKET STREET  
PHILADELPHIA, PA. 19104  
(215) 387-8400

January 3, 1979

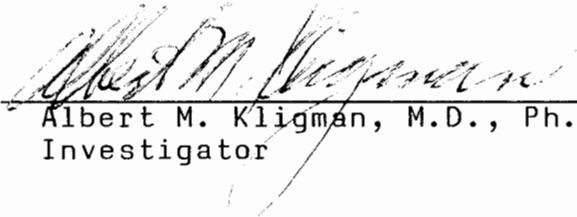
IVY RESEARCH PROTOCOL: #3791 submitted August 23, 1978

WOUND HEALING ASSAY

CONCLUSIONS:

We have reviewed the re-epithelialization grading on Thomas Coffey and have concluded that due to the fact that this grading was made on an open wound (control), it is our opinion that the changes noted on day 7, day 9 and day 11 were probably due to wound breakdown and recovery caused by environmental changes.

The dermatoglyphic grading on Kurt Klopp of one week and nine days was a typo error and both should be a grade two (2).

  
Albert M. Kligman, M.D., Ph.D.  
Investigator

AMK/mjm

## KEY TO NUMBER VALUES IN GIVEN PARAMETERS

RATING: WILL BE DONE BY A NUMBER OF ONE TO THREE.

- 1- BEST
- 2- GOOD
- 3- BAD

THESE NUMBERS WILL BE GIVEN BY THE MONITOR TO INDICATE WHICH WOUND LOOKS THE BEST ON ANY GIVEN DAY OF EVALUATION.

ERYTHEMA: WILL BE GRADED ON A SCALE OF ONE TO THREE.

- 1-MILD
- 2-MODERATE
- 3-SEVERE

RE-EPITHELIALIZATION: WILL BE GRADED STRICTLY ON A PERCENTAGE BASIS, IN RESPECT TO THE ENTIRE WOUND SURFACE.

DERMATOGLYPHICS: WILL BE GRADED ON A ZERO TO FIVE SCALE.  
(SKIN MARKINGS)

- 0- NO SKIN MARKINGS VISIBLE
- 1- MAJOR LINES BEGINNING AT THE WOUNDS BORDERS.
- 2- MAJOR LINES 50% OF THE ENTIRE WOUND SURFACE.
- 3- MAJOR LINES ENTIRE WOUND SURFACE.
- 4- MAJOR LINES THROUGHOUT WITH MINOR LINES BEGINNING.
- 5- MAJOR AND MINOR LINES THROUGHOUT.

N.B. THE GRADING FOR DERMATOGLYPHICS WILL NOT BEGIN UNTIL THE WOUND IS 100% RE-EPITHELIALIZED.

WOUND DEPRESSION: THE DEPTH OF THE WOUND AS EXAMINED THROUGH THE STERO

MICROSCOPE.

- 0- NO DEPRESSION AT ALL WOUND SURFACE EVEN WITH SURROUNDING SKIN.
- 1- 75% FILLED IN.
- 2- 50% FILLED IN.
- 3- 25% FILLED IN OR LESS.

JEN 1978

WOUND HEALING ASSAY

NAME: K.J. AGE: 21 RACE: White SEX: Male START: 11/27/78 FINISH: 12/18/78

SITE MATERIALS	RATING	ERYTHEMA	RE-EPITH	DERMATOGLYPHICS	WOUND DEPRESS.	COMMENTS	DAY OF EVALUATION
Aloe Extract w/Quinone	3	0%	0	3			24 Hours
Aloe butter Body Cream	3	0%	0	3			
Body Cream Base	3	0%	0	3			
Body Cream w/Quinone	3	0%	0	3			
Aloe Vera Extract	3	0%	0	3			
Telfa No Treatment	3	0%	0	3			
Open Control	3	0%	0	3			
Aloe Extract w/Quinone	2	50%	0	3			
Aloe butter Body Cream	3	50%	0	3			
Body Cream Base	3	50%	0	3			
Body Cream w/Quinone	3	25%	0	3			72 Hours
Aloe Vera Extract	3	50%	0	3			
Telfa No Treatment	3	90%	0	3			
Open Control	3	0%	0	3			





WOUND HEALING ASSAY

NAME: K.J. AGE: 21 RACE: White SEX: Male START: 11/27/78 FINISH: 12/18/78

SITE	MATERIALS	RATING	ERYTHEMA	RE-EPITH	DERMATOGLYPHICS	WOUND DEPRESS.	COMMENTS	DAY OF EVALUATION
	Aloe Extract w/Quinone	1	100%		4	1		
	Aloe Butter Body Cream	1	100%		4	1		
	Body Cream Base	1	100%		2	1		
	Body Cream with Quinone	1	100%		3	1		2 Weeks
	Aloe Vera Extract	0	100%		4	1		
	Telfa No Treatment	1	100%		3	1		
	Open Control	2	100%		1	1		
	Aloe Extract with Quinone	1	100%		3	0		
	Aloe Butter Body Cream	1	100%		3	0		
	Body cream Base	1	100%		3	0		3 Weeks
	Body Cream with Quinone	1	100%		4	0		
	Aloe Vera Extract	0	100%		5	0		
	Telfa No Treatment	0	100%		4	0		
	Open Control	2	100%		3	1		











WOUND HEALING ASSAY

NAME: E.S. AGE: 22 RACE: White SEX: Male START: 11/27/78 FINISH: 12/18/78

SITE	MATERIALS	RATING	ERYTHEMA	RE-EPITH	DERMATOGLYPHICS	WOUND DEPRESS.	COMMENTS	DAY OF EVALUATION
	Aloe Extract w/Quinone	3	0%		0	3		24 Hours
	Aloe Butter Body Cream	3	0%		0	3		
	Body Cream Base	3	0%		0	3		
	Body Cream with Quinone	3	0%		0	3		
	Aloe Vera Extract	3	0%		0	3		
	Open Control	3	0%		0	3		
	No Telfa Treatment	3	0%		0	3		
	Aloe Extract w/Quinone	3	75%		0	3		
	Aloe butter Body Cream	3	75%		0	3		
	Body Cream Base	3	50%		0	3		
	Body Cream w/Quinone	3	75%		0	2		
	Aloe Vera Extract	3	75%		0	3		
	Open Control	2	10%		0	3		
	Telfa No Treatment	3	50%		0	3		

72 Hours

WOUND HEALING ASSAY

FINISH: 12/18/78

START: 11/27/78

Male

SEX:

White

RACE:

AGE: 22

NAME: E.S.

DAY OF  
EVALUATION

WOUND  
DEPRESS. COMMENTS

DERMATOGLYPHICS

RATING ERYTHEMA RE-EPITH

SITE MATERIALS

SITE MATERIALS	RATING ERYTHEMA	RE-EPITH	DERMATOGLYPHICS	WOUND DEPRESS. COMMENTS	DAY OF EVALUATION
Aloe Extract with Quinone	2	100%	1	2	96 Hours
Aloe Butter Body Cream	2	100%	1	2	
Body Cream Base	2	95%	1	2	
Body cream w/Quinone	2	100%	1	1	
Aloe Vera Extract	2	100%	1	2	
Open Control	3	25%	0	3	
Telfa No Treatment	2	75%	1	2	
Aloe Extract w/Quinone	2	100%	2	2	
					1 Week
Aloe Butter Body Cream	2	100%	2	2	
Body Cream Base	3	100%	1	2	
Body Cream w/Quinone	3	100%	2	1	
Aloe Vera Extract	1	100%	2	2	
Open Control	3	75%	0	3	
Telfa No Treatment	2	100%	1	2	















TERRY CORPORATION

WOUND HEALING EVALUATION OF ALOE VERA EXTRACTS

Ivy Research Protocol: #3791

Conducted: July 10, 1978 through  
July 31, 1978

METHOD:

Seven blisters were induced on the volar forearms of two adult white male volunteers and a third volunteer (male) received eight (8) blisters (using the ammonium hydroxide blister technique by Frosch and Kligman, British Journal of Dermatology, Vol. 96, pages 461-473, 1977).

Immediately, the blister roofs were removed and the sites treated with (1) Aloe Vera Extract, (2) Aloe Vera Extract with Quinone, (3) Aloe Vera Butter Body Cream, (4) Aloe Vera Butter Body Cream with Quinone, (5) Aloe Vera Butter Body Cream Base, (6) Lanolin (Hydrous USP Lannett), (7) an open control - and, one subject was treated with (8) TELFA and tape alone.

The wounds were each covered with the appropriate material - a TELFA dressing and permeable Micropore tape which were changed every 48 hours. Wound healing was evaluated during treatment at 24 hours and every 48 hours thereafter for a two week period with a follow-up examination at three weeks.

The wounds were evaluated with a dissecting stereo microscope (Zeiss) under a magnification of 6-40X. Photographic slides were also taken at intermittent intervals. The grading was as follows:

Erythema	0 - 3
Re-epithelization:	Percentage of entire wound surface
Dermatoglyphics:	0 - 5
Wound depression:	0 - 3

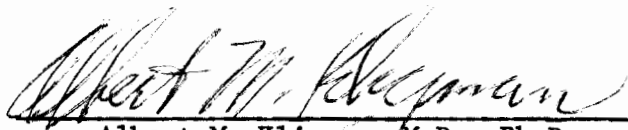
The key to number values is included in the enclosed Tables.

CONCLUSION:

It is our opinion that the Aloe Vera Extracts tested did not interfere with the normal rate of superficial wound healing, nor did they enhance the healing process any faster than a Lanolin control.

It can be stated that the materials were superior to an untreated, uncovered wound and marginally better than one TELFA covered wound.

Respectfully submitted,

  
Albert M. Kligman, M.D., Ph.D.  
Investigator

8-23-78

Date

AMK/mjm

KEY TO NUMBER VALUES IN GIVEN PARAMETERS

RATING: WILL BE DONE BY A NUMBER OF ONE TO THREE.

- 1- BEST
- 2- GOOD
- 3- BAD

THESE NUMBERS WILL BE GIVEN BY THE MONITOR TO INDICATE WHICH WOUND LOOKS THE BEST ON ANY GIVEN DAY OF EVALUATION.

ERYTHEMA: WILL BE GRADED ON A SCALE OF ONE TO THREE.

- 1-MILD
- 2-MODERATE
- 3-SEVERE

RE-EPITHELILIZATION: WILL BE GRADED STRICTLY ON A PERCENTAGE BASIS, IN RESPECT TO THE ENTIRE WOUND SURFACE.

DERMATOGLYPHICS: WILL BE GRADED ON A ZERO TO FIVE SCALE.  
(SKIN MARKINGS)

- 0- NO SKIN MARKINGS VISIBLE
- 1- MAJOR LINES BEGINNING AT THE WOUNDS BORDERS.
- 2- MAJOR LINES 50% OF THE ENTIRE WOUND SURFACE.
- 3- MAJOR LINES ENTIRE WOUND SURFACE.
- 4- MAJOR LINES THROUGHOUT WITH MINOR LINES BEGINNING.
- 5- MAJOR AND MINOR LINES THROUGHOUT.

N.B. THE GRADING FOR DERMATOGLYPHICS WILL NOT BEGIN UNTIL THE WOUND IS 100% RE-EPITHELILIZED.

WOUND DEPRESSION: THE DEPTH OF THE WOUND AS EXAMINED THROUGH THE STERO

MICROSCOPE.

- 0- NO DEPRESSION AT ALL WOUND SURFACE EVEN WITH SURROUNDING SKIN.
- 1- 75% FILLED IN.
- 2- 50% FILLED IN.
- 3- 25% FILLED IN OR LESS.

JEN 1978