CUTIMED EPIONA®

CLINICAL STUDY 28 OCTOBER – 11 DECEMBER 2015

QUICK OVERVIEW

- Clinical study evaluated the effectiveness of Cutimed Epiona® when administered with standard of care, based on wound etiology, of 31 patients
- Study performed up to 4 weeks at wound care centers in the U.S.
- Primary endpoint was reduction in wound area
- Wounds were mainly diabetic foot ulcers (DFUs; 42%) and venous leg ulcers (VLUs; 32%); the remainder were other types of chronic wounds
- Mean age of wounds at first visit was 301 days; mean reduction in wound area after 3 weeks was almost 40%
- Change in wound area from Week 1 to Week 3 was statistically significant (p=.006)
- 30 of 31 participants completed the study

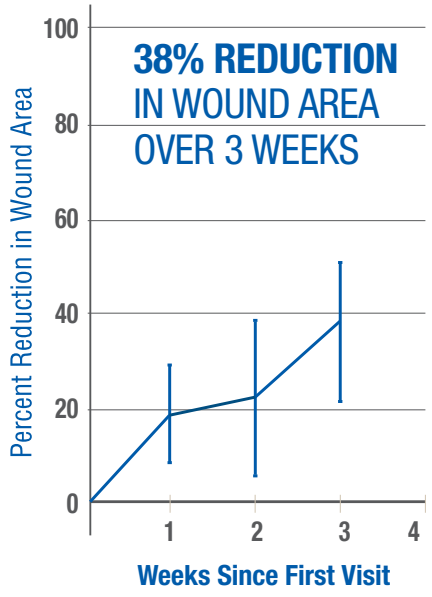
Fast facts on a new 3D matrix™ technology that fast-tracked healing for chronic wounds

Cutimed Epiona®'s native collagen provides structural support with an ECM-like scaffold to promote tissue generation that supports healing of stagnating wounds.

- It transforms into a flexible, moist gel covering when exposed to wound exudate or blood
- It acts as a "sacrificial substrate" in the wound, so MMPs affix to the dressing and are reduced in the wound fluid
- It supports formation of granulation tissue and epithelialization

Compelling Results

- Mean reduction in wound area after 3 weeks was almost 40% in wounds that had stalled with a mean wound age of 301 days
- Fourteen of the wounds were reduced by 50% or more after 3 weeks
- Complete wound healing occurred in 3 wounds, 2 and 3 weeks after the first visit
- No infections or adverse events were reported
- Change in wound area compared at Week 1 and Week 3 was statistically significant (p=.006)

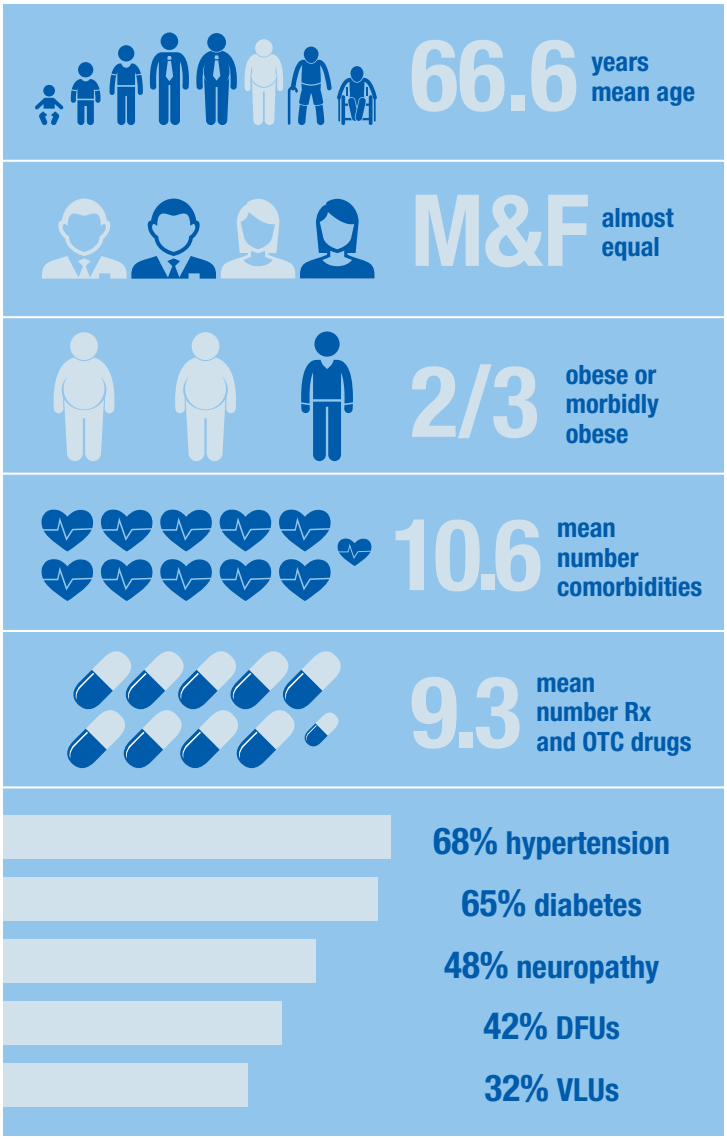


Percent reduction in wound area by week.
Vertical bars represent 95% confidence intervals.

Cutimed®

All Participants Had Multiple Serious Comorbidities Likely to Slow Wound Healing

SUBJECT SNAPSHOTS



Patient Variable	Count (%)	Mean/Median (SD)
Gender		
Male	15 (48)	
Female	16 (52)	
Race		
Caucasian	28 (90)	
African American	3 (10)	
Drug Count		**9.3/9 (5.64)**
Selected Drug Categories		
For pain	19 (61)	
For neuropathic pain	13 (42)	
Pain for wound	1 (3)	
For diabetes	15 (48)	
For dyslipidemia/high cholesterol	15 (48)	
For mental illness	7 (23)	
For renal disorders	2 (7)	
For hypertension	23 (74)	
Wound Variable	**Count (%)**	**Mean/Median (SD)**
Type		
DFU (diabetic foot ulcer)	13 (42)	
VLU (venous leg ulcer)	10 (32)	
Traumatic	4 (13)	
PU (pressure ulcer)	2 (7)	
Mixed	1 (3)	
Surgical	1 (3)	
Initial area (cm2)		
All		4.8/1.8 (8.38)
DFU (diabetic foot ulcer)		2.1/1.5 (1.68)
VLU (venous leg ulcer)		8.9/2.3 (13.21)
Traumatic		1.6/1.5 (1.13)
PU (pressure ulcer)		0.5
Mixed		15.8
Surgical		11.2

INCLUSION CRITERIA

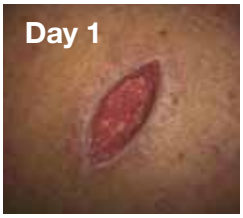
1. Male or female subjects > 18 years old
2. Subjects with a chronic wound (pressure ulcer, diabetic ulcer, venous ulcer, ulcers caused by mixed vascular etiologies, second-degree burns, donor and graft sites, abrasions, dehisced surgical wounds or traumatic wounds healing by secondary intention)
3. Subjects who agreed to participate in the study, including all study-related procedures and evaluations, and documented agreement by signing the IRB-approved informed consent

EXCLUSION CRITERIA

1. Subjects with a known sensitivity or allergy to bovine collagen or one of the other product contents
2. Subjects whose wounds were third-degree burns, covered in eschar or dead tissue
3. Subjects who were not willing or able to consent or participate
4. Subjects who received an experimental drug or used an experimental medical device within seven days prior to the planned start of treatment
5. Employees of the Investigator or study center with direct involvement in the proposed study or other studies under the direction of that Investigator or study center

Rapid Clinical Results on Chronic Wounds

Patient #1 – Surgical Wound



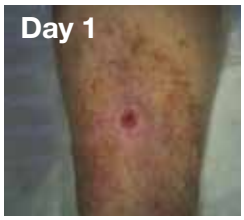
Patient was a 78-year-old male with a chronic ulcer on the upper back (surgical wound), four weeks in duration. Patient presented with a history of hypertension, type II diabetes, melanoma of the upper back (removed) and dyslipidemia. The wound had severe drainage at screening, with a wound area of 11.2 cm^2.

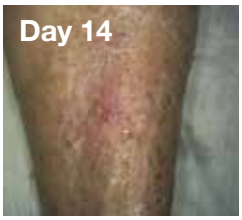
Study evaluated the effectiveness of Cutimed Epiona® Native Collagen Dressing. Adjunct therapy included standard care (debridement, cover dressing).

Debridement was performed as needed throughout the study. Patient was seen weekly from Visits 1-4 with wound area decreasing throughout the study duration.

- Day 1 wound area 11.2 cm^2
- Day 21 wound area 1.4 cm^2
- Total Wound Area Reduction 87.1% from day 1

Patient #2 – Venous Leg Ulcer





Patient was a 73-year-old female with a venous leg ulcer on the right leg, nine months in duration. Patient presented with a history of hypertension, type II diabetes and diabetic neuropathy. The wound had moderate drainage at screening with a wound area of 1.1 cm^2.

Study evaluated the effectiveness of Cutimed Epiona® Native Collagen Dressing. Adjunct therapy included standard care (debridement, cover dressing and compression).

Patient was seen weekly from Visits 1-4 and presented with a closed wound at Visit 3, which remained closed at Visit 4.

- Day 1 wound area 1.1 cm^2
- Day 14 wound area completely closed
- Total Wound Area Reduction 100% from day 1

Patient #3 – Diabetic Foot Ulcer

Patient was a 53-year-old male with a right, distal, plantar diabetic foot ulcer, four months in duration. Patient presented with a history or type II diabetes, diabetic neuropathy, hypertension, transmetatarsal amputation (TMA), cholecystectomy, tubes in ears, left knee meniscus repair and vasectomy. The wound had mild drainage at screening (Visit 1) with a wound area of 1.8 cm^2.

Study evaluated the effectiveness of Cutimed Epiona® Native Collagen Dressing. Adjunct therapy included standard care (debridement, cover dressing, Total Contact Casting).

The patient was seen weekly from Visits 1-4 with wound area decreasing throughout the study duration.

- Day 1 wound area 1.8 cm^2
- Day 21 wound area 0.5 cm^2
- Total Wound Area Reduction 71.8% from Day 1

Change in wound exudate level by week:

Week	None	Minimal	Moderate	Heavy
1	0 (0)	18 (58)	11 (35)	2 (7)
3	5 (16)	18 (58)	8 (26)	0 (0)

Cutimed Epiona®: Compelling Clinical Results

Primary Endpoint

- Reduction in wound area

Secondary Endpoints

- Rate of wound healing over time
- Amount of granulation over time
- Ease of study product application
- Number of dressing changes over time
- Adverse events
- Pain

Study Methodology

An intent-to-treat (ITT) approach was used for analyses. For missing observations, the last observation carried forward (LOCF) principle was used. For wounds that healed, the following variables were set to 0 at Week 3: area, pain, exudate level. Study variables were summarized as means and standard deviations (SDs) for continuous variables unless data were non-normal, as determined by the Shapiro-Wilk test, in which case medians were also reported, and proportions or percentages of categorical variables. Paired tests were used to compare trial endpoints if data were normal, and the Wilcoxon signed rank test data were non-normal, and differences existed. To adjust for the family-wise error rate (FWER), p values were reported using the Hochberg step-up procedure. Adjusted two-side p values < 0.05 were considered significant. PASW 19 (IBM, Chicago, IL) was used to perform the statistical testing.

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