WUWHS
World Union of Wound Healing Societies
Florence, Italy
September 25-29, 2016

New collagen dermal substitute*: our experience

ISTITUTI CLINICI ZUCCHI

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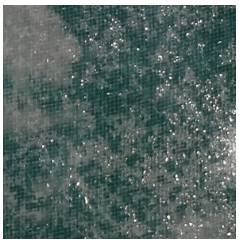
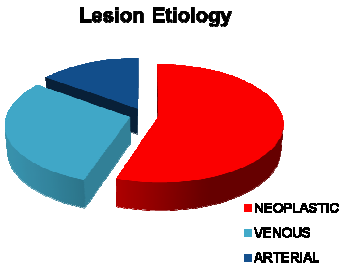


This study reports our experience on use of a new dermal substitute (DS) made of a bi-layer matrix of collagen and silicone, without containing glycosaminoglycan.

Methods

We recruited 43 patients between 2014 and 2016 with chronic wounds, refractory or contraindicated to other kinds of therapy (wound dressings, skin grafts, flaps), treated surgically with this DS .



Patient were followed and observed for a period of time of at least 60 days or until complete healing, with five clinical evaluation times.evaluation times: T0 (entry in the study), T1 (21 days+/-2), T2 (28 days+/-4), T3 (40 days+/-7), T4 End (60 days +/-7).

Patients were observed at different times: 21 days it was made a coverage with dermo-epidermal graft when an adequate bed score was reached.

We considered the following parameters: amount of granulation tissue, Wound Bed Score (WBS) and onset of complications. Patients who underwent other treatments were excluded from the study. A retrospective chart review was performed, including every case in which this new DS was used. Inclusion criteria were independent of sex, ethnicity, and physical or mental condition (table 1).

At the entry in the study (T0) all anamnestic data were collected: age, sex, smoke, comorbidities (diabetes, high pressure, renal failure, vascular problems, autoimmune diseases, neurologic diseases, cardiac problems, burns). Etiology, number and location, presence of infection, perilesional skin, borders, wound bed and exudate (WBAS, WES)12, wound bed score (WBS)13 were described and registered for every lesion.

LOCATION OF WOUND	
LOWER LIMB	68%
UPPER LIMB	3.1%
SCAPULAR REGION	3.1%
LUMBOSACRAL REGION	6.5%
FEET	13%
ACHILLEAN REGION	3.1%
STERNAL REGION	3.1%

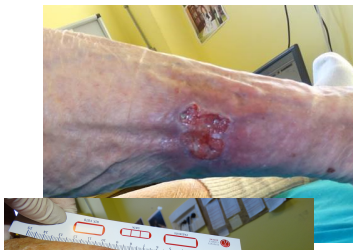
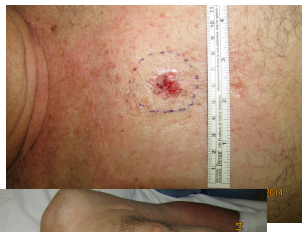
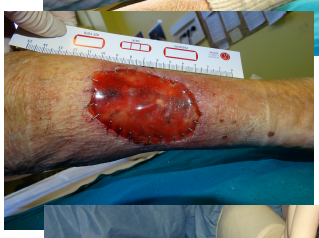
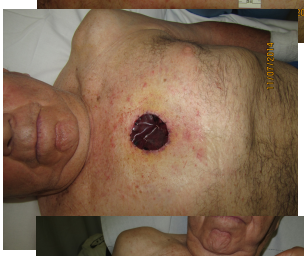
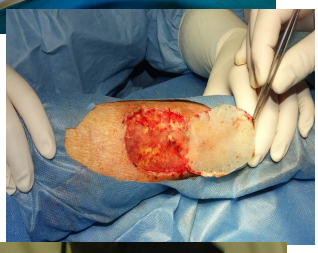
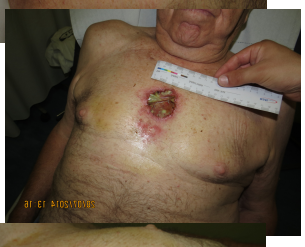
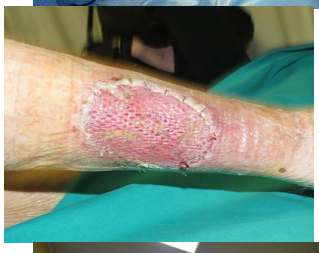
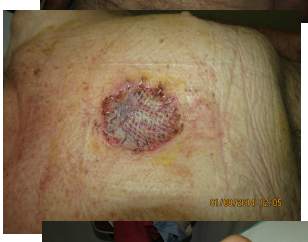
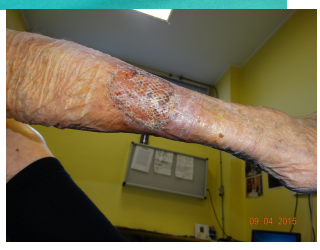
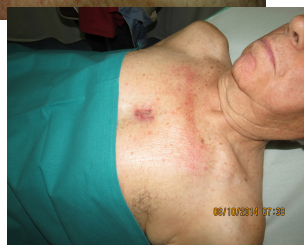
Endpoints

Primary endpoint of the study was to determine the variation of wound dimension versus T0 and healing rate.

Secondary endpoints included the evaluation of mean time of complete healing, variation of wound bed and exudate determining the Wound Bed Appearance Score and Wound Exudate Score, variation of Wound Bed Score12-13 (table 3, 4, 5).

INCLUSION CRITERIA	EXCLUSION CRITERIA
1. BOTH SEXES	1. CLINICAL SIGNS OF INFECTION
2. AGE > 18 YEARS	2. ACUTE WOUNDS
3. SKIN CHRONIC WOUNDS	3. PREGNANCY
4. LESIONS IN ANY AREA	4. LACK OF INFORMED CONSENT
5. INFORMED CONSENT	
6. LESIONS UNTREATABLE WITH OTHER THERAPIES	

Wound Bed Score (WBS)	0	1	2
Black eschar	>25%	1-25%	0%
Eczema/dermatitis	Severe	Moderate	Absent
Depth	Severe	Moderate	Only depressed
Scarring	Severe	Moderate	Mild
Color of bed (% pink colored granulation tissue)	>50%	50-75%	>75%
Oedema/ swelling	Severe	Moderate	Mild
Resurfacing epithelium	<25%	25-75%	>75%
Exudate amount	every e		

Results:

- 1 patient was excluded
- 2 patient was lost during follow-up
- 3 patients did not underwent a dermo-epidermal graft due to an inadequate WBS
  - 78% of patients fully recovered (34) at T4 (60 days)
  - Recover mean time : 65 days (35-120)

At T1, dermo-epidermal skin graft was performed in 39 patients (90%). After removing the silicone layer at T1, 13.8% OF patients underwent application of a hyaluronic acid matrix because an adequate WBS had not been reached.

We evaluated the occurrence of complications in post-surgical period and during the follow-up.

- We didn't observe systemic complications or adverse events during the period of observation.
- We registered some local complications: bleeding occurred in 20.7% of patients within the 3rd post-surgical day. In particular, the patient affected by the sternal lesion was subjected to post-surgical bleeding in 1st day after surgery, which required frequent changes of absorptive dressing (in this case, polyurethane foam).
- In 6.9% of cases we observed a minimal retraction of the silicone layer, which however did not require reoperation or special precautions.
- None of these patients required reoperation. The DS showed greater stability than other dermal substitutes even in case of complications. In fact, though bleeding or minimal retraction of the superficial film, the DS remained fixed on site of application and the final results were satisfactory.

Evaluating secondary endpoints:

Wound Bed Appearance score improved in 86.2% of cases: in 4 cases in fact after the removal of silicone layer at T1 we couldn't perform a skin graft because of inadequate wound beds.

Wound Bed Exudate score improved in 100% of cases.

Wound Bed Score improved in 100% of cases.

Conclusions

The retrospective study on the use of this new DS brought to clinical evidences and interesting surgical perspectives. The possibility of recreate a dermis that replaces the original one opens new windows of action for modern Reconstructive medicine and surgery. After the restoration of a new dermis, the wound bed in the majority of cases is ready to receive a skin graft. In fact it has been very effective in reducing depth and wound area, controlling exudate, increasing granulation tissue and promoting neoangiogenesis. This procedure has proven to be able to reduce time of recovery and healing of chronic wounds.

Globally, the cellular therapy with skin substitutes showed reduction of skin lesion dimension, increase in WBS, improvement of amount of exudate, improvement of amount of granulation tissue, control of local infection.

Though based on a small number of patients, this study represents a starting point to define the role of this new DS in the treatment of skin lesions.

* Nevelia , Symatese

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