A New Bedside Electrospun Temporary Skin-like Matrix in Second Degree Burns

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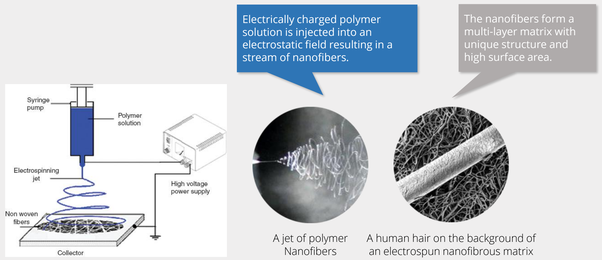
What is Electrospinning?

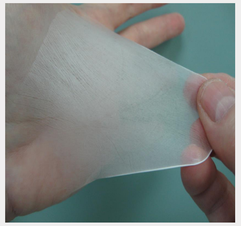
A method of producing nanofibers from natural/synthetic polymer solutions;
Mimicking the architecture of the ECM



The Spincare™ System

Temporary skin-like matrix

A hand-held, battery-operated, portable bedside electrospinning device and
A pre-filled sterile, disposable, single patient, single use polymer-based ampule

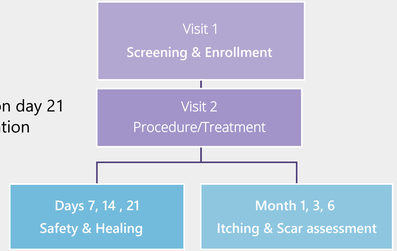


- Temporary Skin-like Matrix
- No-contact application
- Reduces the potential for infection
- Excellent adherence
- Rare dressing changes
- Highly permeable and breathable
- Transparent, allowing through wound evaluation
- Early showers
- Self peeling as epitelialisation is complete

Study Design

A prospective single arm, safety and efficacy, open labeled multi-center study.
Study population: patients with partial thickness burn wounds; second degree superficial to intermediate) of up to 10% TBSA; of which the target wound for treatment is of up to 5% TBSA

- 3 medical centers in Israel;
- Total of 44 patients;
- 6 months FU.



Primary End point

- Wound healing and re-epithelization on day 21
- Visual assessment: ≥ 95% re-epithelization

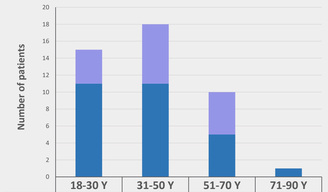
Secondary end points

- Ease of use
- Dermal safety (Draize score)
- Pain (VAS)
- Infection
- Itching (VAS)
- Scaring (Vancouver scale) up to 6 months
- Device related AE

Study Demographics

- N=44 patients recruited
- Mean age of 40Y (18-86)
- 28 Male and 16 Female
- Average burn injury 6.25% TBSA
- Average burn treated 3.65% TBSA

Age and Gender

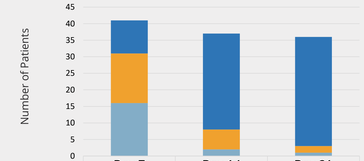


	18-30 Y	31-50 Y	51-70 Y	71-90 Y
Female	4	7	5	0
Male	11	11	5	1

Study Results

- Pain was reduced immediately after dressing from 2.8 to 1.6 (VAS scale)
- Ease of use 1.3 (scale of 5)
- No SAE; 17 AE; no device-related adverse events were reported

Healing Progress (%Healing per FU day)



	Day 7	Day 14	Day 21
95%- 100%	10	29	33
51%- 94%	15	6	2
0%- 50%	16	2	1

Patient history*

Male, 44Y old; 2nd degree superficial to intermediate flame burn. Milton and Saline cleansing prior to Spincare layer application. No secondary dressing applied.

Patient history*

Male 41Y, no pervious medical history; 2nd degree mixed superficial to intermediate burn (radiator boiled water). Spincare layer applied with excellent adherence and fit to this hard to dress area. No secondary dressing applied. **Physiotherapy initiated during healing process.**
*Rambam Medical Center, Israel

Conclusions

The nanofibrous temporary skin-like layer is tailored to the shape and morphology of the wound with excellent adherence; Opaque upon application, becoming transparent, allowing evaluation of wound bed without removal.

Large, hard-to-dress burn wounds are easily treated with the electrospun matrix, a minimally painful treatment option and effective healing, with excellent adherence even in challenging contours, free movement and regular showers; applied one time and peels off on its own when healing is complete. Larger clinical scale data will be needed to further confirm these results.

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