

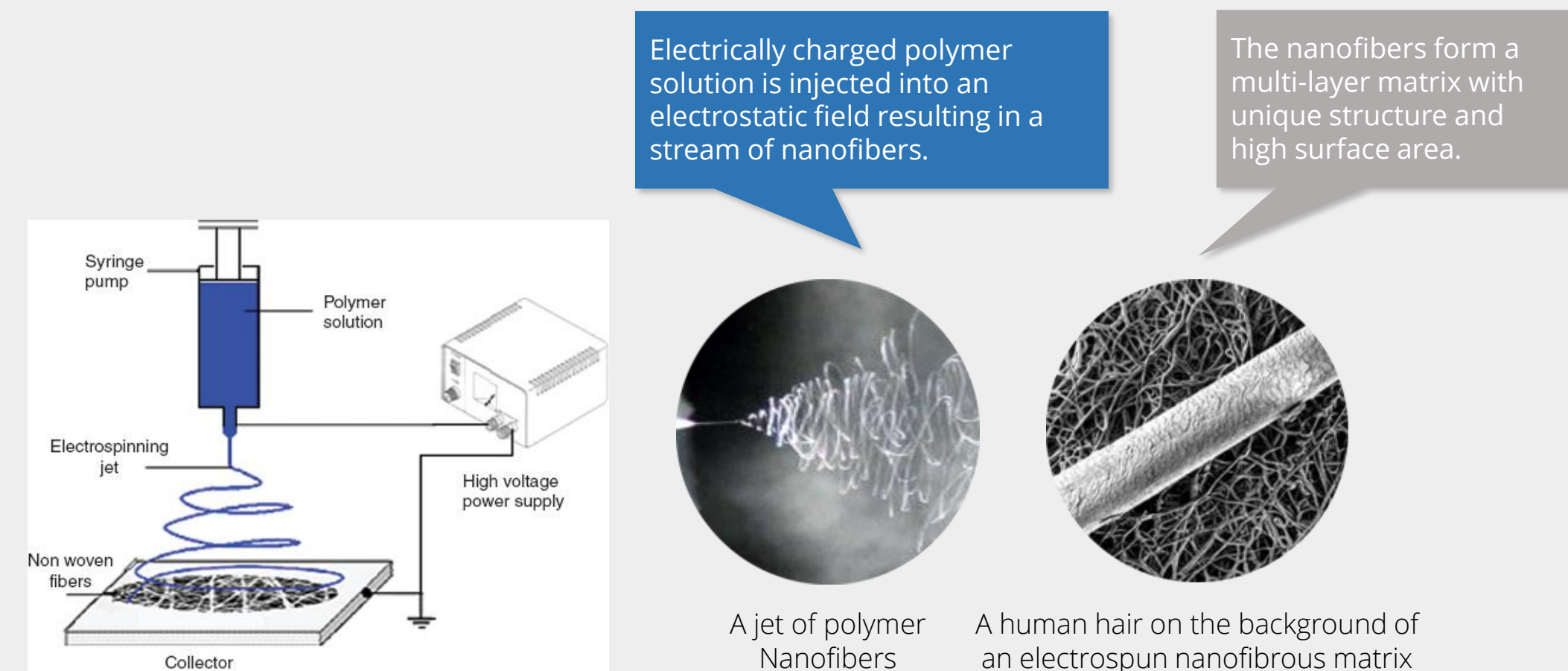
# A New Bedside Electrospun Temporary Skin-like Matrix in Second Degree Burns

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## What is Electrospinning?

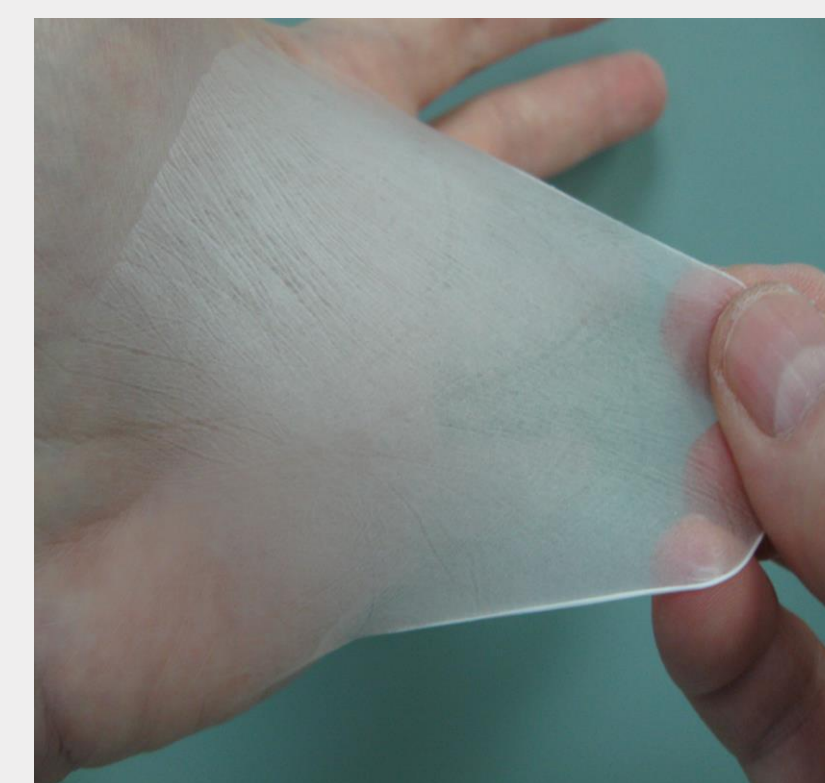
A method of producing nanofibers from natural/synthetic polymer solutions; Mimicking the architecture of the ECM



## 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 epithelialisation 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

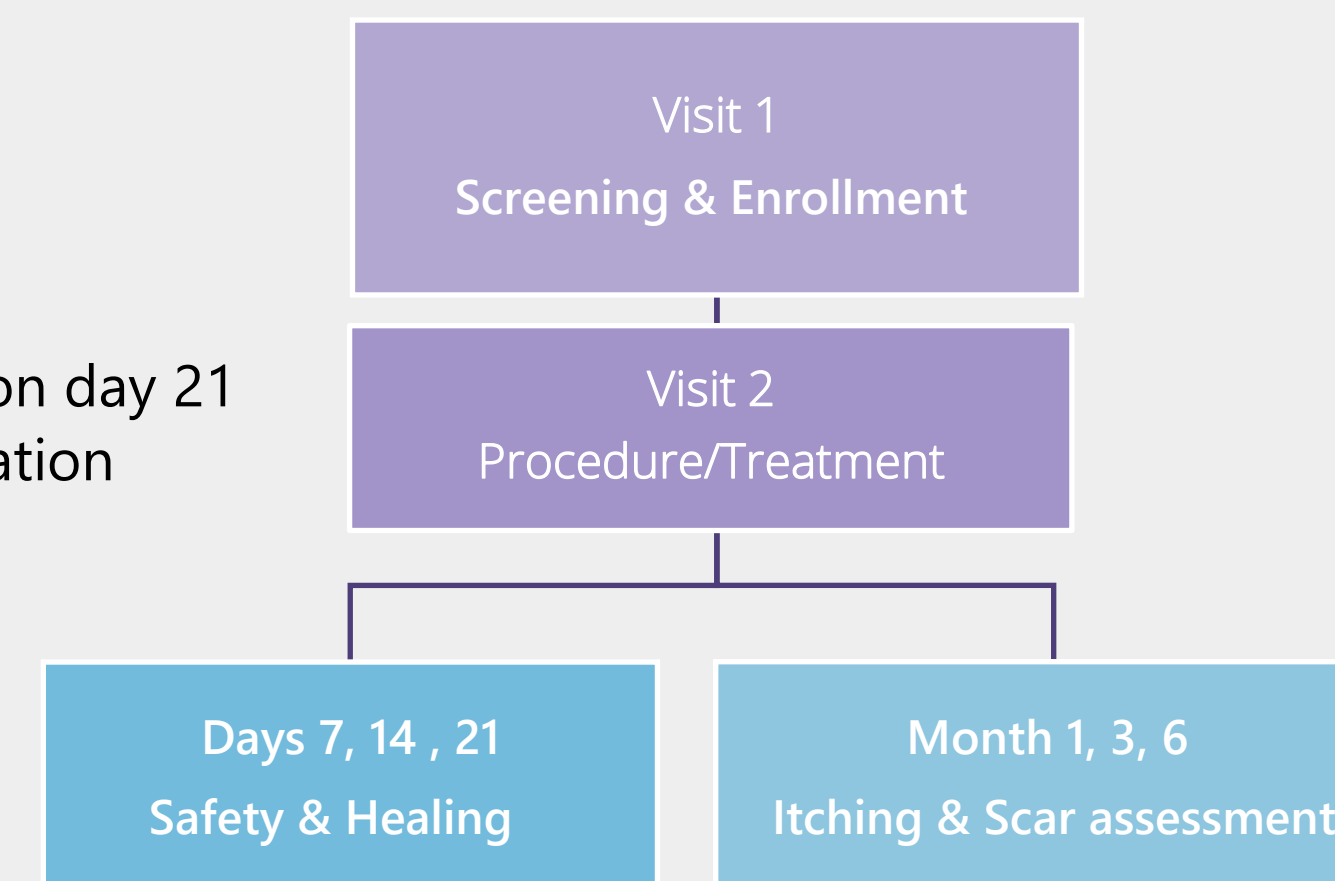
- ✓ 3 medical centers in Israel;
- ✓ Total of 44 patients;
- ✓ 6 months FU.

### Primary End point

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

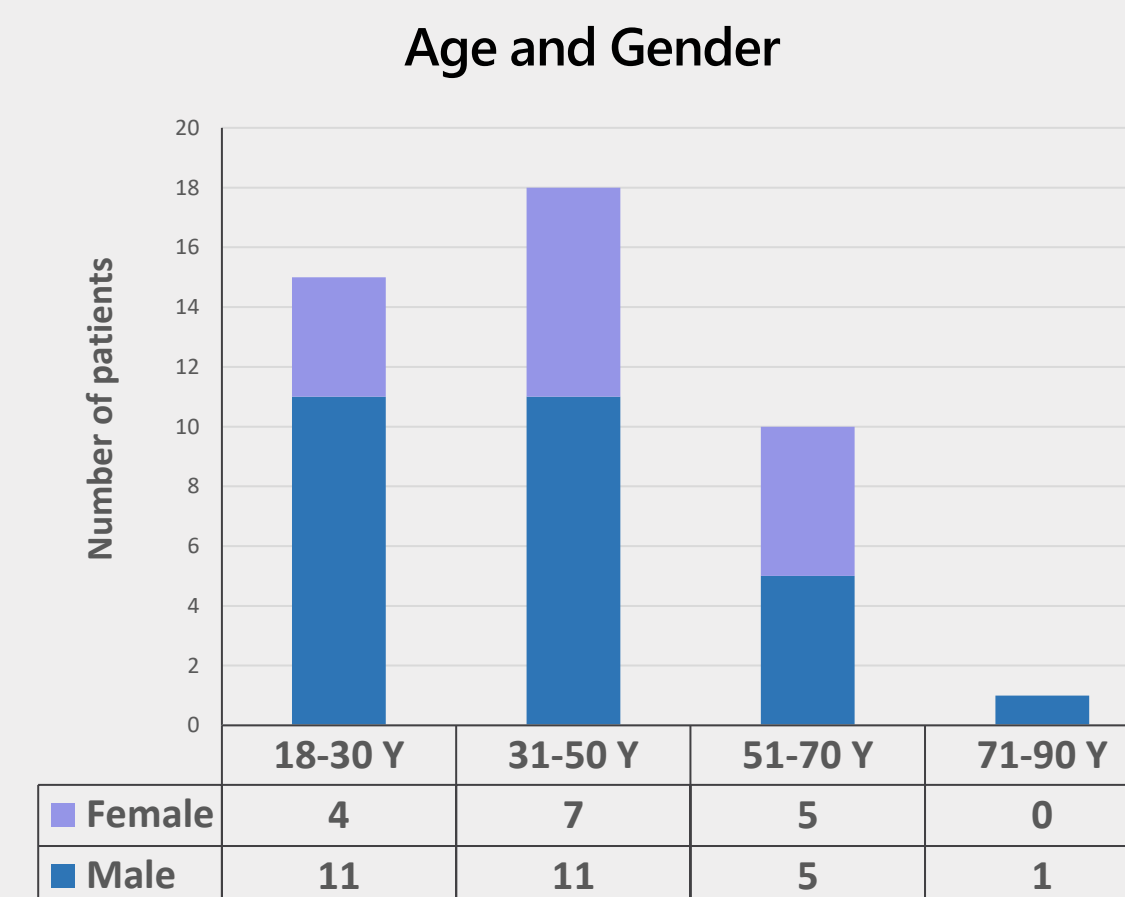
### Secondary end points

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



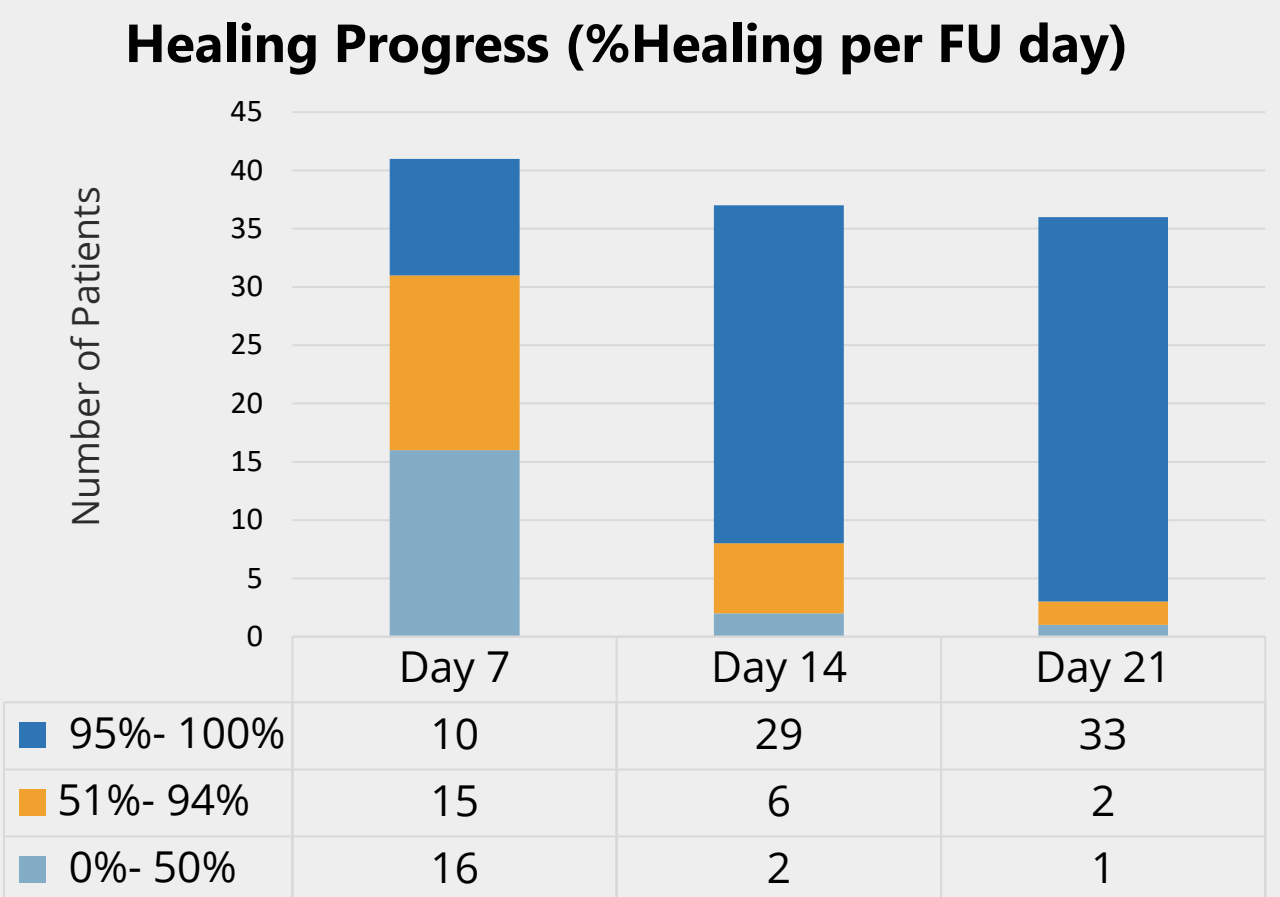
## Study Demographics

- ✓ 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



## 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



### 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 previous 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.**

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## 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.