PROSPECTIVE FOLLOW-UP STUDY :

SAFETY AND EFFICACY OF NEVELIA® IN THE TREATMENT OF THIRD-DEGREE BURNS TREATMENT OR RECONSTRUCTIVE SURGERY

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Primary objective

Assessment of the type and frequency of complications related to NEVELIA®

Secondary objectives

- To assess the take rate of NEVELIA®
- To assess the take rate of dermo-epidermal graft
- To assess the satisfaction rate of physician and patient (VAS scale)
- To assess the quality of the regenerated skin (Score of Vancouver)
- To assess the rate of re-intervention at 12 months

Follow-up assessment

Day -15 to Day-1	Inclusion – Informed consent signature
Day 0	**Dermal substitute implantation**
Post-implantation visit	Photo, type and size of the wound *(Serious) Adverse Event reporting*
Day 21(+/-7days)	**Skin graft** Photo, graft type, matrix take rate
Post-implantation visit	Photo, graft take rate, *(Serious) Adverse Event reporting*
F-U 6M F-U 12M	Photo, graft take rate Vancouver score Patient and Surgeon satisfaction *(Serious) Adverse Event reporting*

Study progress

Favorable opinion of EC: December 2013

- Study Initiation in Bordeaux: April 2014
- Substantial amendment: December 2014

  => Study Initiation in Montpellier: February 2015

- 33 patients included between May 2014 and Feb 2015:
  - 28 patients in Bordeaux
  - 5 patients in Montpellier
- 33/33 FU 6M done
- 31/33 FU 12M done (2 loss of follow-up)
- End of study (last 12M FU) = Feb 2016

- 10 females mean age 46 years
- 23 males mean age 57 years

- Types of wound: **trauma** (80%), carcinoma resection, diabetic foot, ulcer, burns

- Final report: End of 2016

Study population & Indications

INDICATIONS	Number of patients (%)
RECONSTRUCTIVE SURGERY (30 PATIENTS)	
Trauma and delayed wound healing	9 (30,0)
Treatment of flap donor site	6 (20,0)
Open wound on amputation strump	5 (16,7)
Wound related to melanoma/epidermoid carcinoma exeresis	4 (13,3)
Diabetic foot	2 (6,7)
Other wounds (Cutaneous necrosis, necrotizing dermohypodermitis)	3 (10,0)
Mixt ulcer	1 (3,3)
THIRD-DEGREE BURNS (3 PATIENTS)	
Foot	2 (6,7)
Hip and buttock	1 (3,3)

Wound Location

Lower limbs: 24 patients

Upper limbs: 9 patients

RESULTS PERFORMANCE OF NEVELIA®

EASE OF USE

91% surgeons were satisfied by use and handling of NEVELIA®

- Negative aspects:
  rigidity +++ (1 patient),
  plicature +++ (2 patients),
  difficulty for silicone removal (1 patient)

PLASTICITY

- Favorable in 79% of cases
- No case of tearing

Fixation of NEVELIA® with staples 97%

- Standard dressing (tulle gras) ± Betadine (85%)
- VAC in 5 patients (15%)

TAKE RATE OF NEVELIA®

81,2%

MEAN TIME BETWEEN NEVELIA® IMPLANTATION AND SKIN GRAFT:

26.5 days [17 – 54]

- Incomplete take rate of NEVELIA® (infection, lysis, residual collagen) <=> DELAY

HIGH SKIN GRAFT TAKE RATE at 12 Months

84,2%

HIGH FUNCTIONAL RESULTS

at 12 Months:

Satisfaction rate of surgeon 76,8%

Satisfaction rate of patient 69,4%

HIGH AESTHETICS RESULTS

at 12 Months :

Satisfaction rate of surgeon 62,7%

Satisfaction rate of patient 55,8%

VANCOUVER SCORE

at 12 Months

4,1 (min: 0 – max: 10)

Templates	Lot Number	Bordeaux (n=28)	Montpellier (N=5)	Total (N=33)
MCS0505 5 x 5 cm	S2132070008 S2141910002	5 (17,9%)	3 (60,0%)	8 (24,2%)
MCS1015 10 x 15 cm	S2141640002	15 (53,7%)	2 (40,0%)	17 (51,6%)
MCS1030 10 x 30 cm	S2132070013	8 (28,7%)	0 (0,0%)	8 (24,2%)

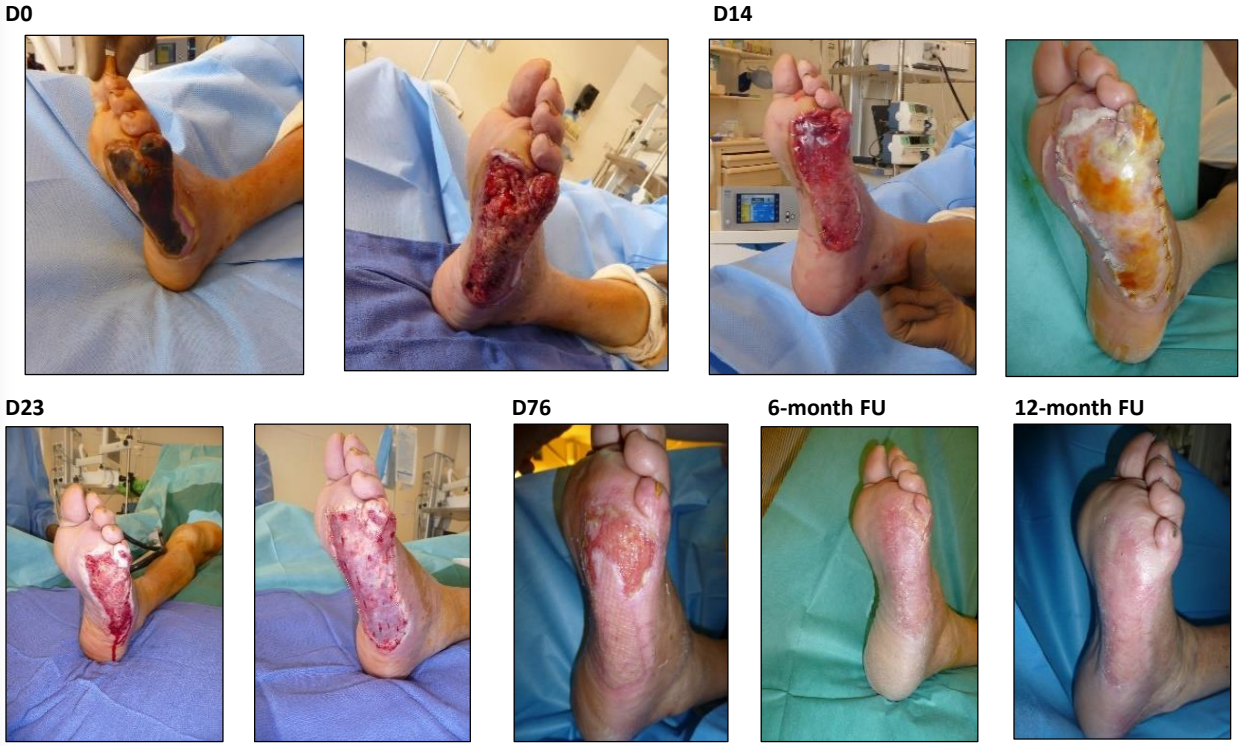
SAFETY OF NEVELIA®

No unknown Adverse Events

Only 4 AE related to NEVELIA® (all described in the IFU): 3 Infections, 1 liquid accumulation under the matrix) The other AEs were related to the pathology or conditions of patient's health: pain, planned surgery (related to the initial surgery), lysis of the graft, pseudoarthrosis

No SAE not related to NEVELIA®

Clinical case #1: Male, 75 yrs old, Third-degree burn (left foot)



Good trophicity especially in an area of friction and pressure

For extended burns waiting for donor site availability

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CONCLUSION

The performance of NEVELIA® is satisfactory

The benefits for the patient are justified (dermal regeneration, wound healing)

Contra-indications and precautions have been specified in the instructions for use to significantly reduce the risks

The risk-benefit ratio is acceptable for the use of the NEVELIA® in the intended use

Clinical case #2: Female, 60 yrs old, Infected chronic wound (right diabetic foot)

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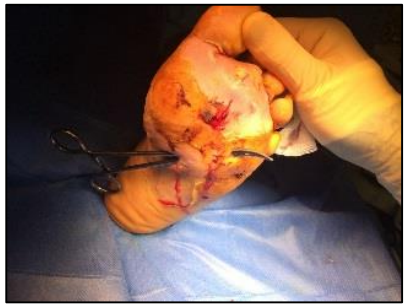

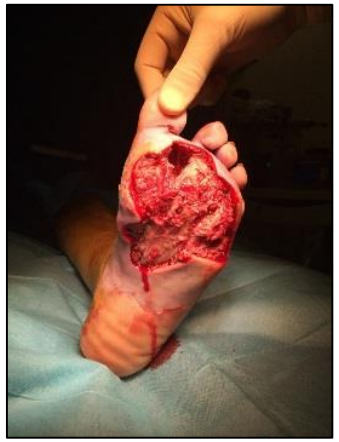

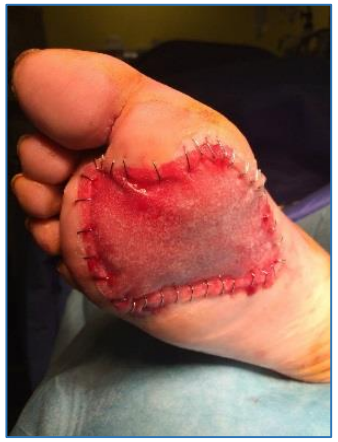

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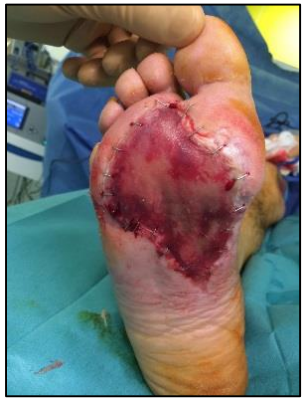

- Good trophicity especially necessary in an area of friction, and pressure
- Adapted to prolonged healing time
- Wound recurrence prevention in shoes

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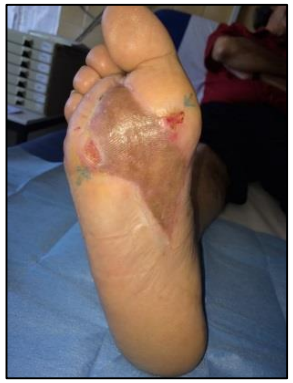
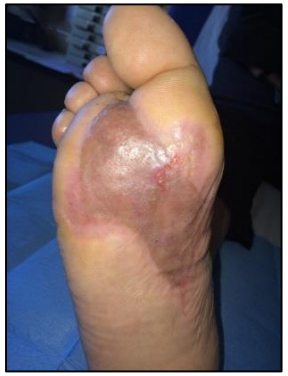
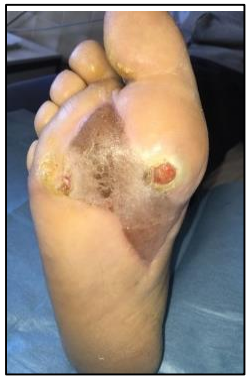
3-month FU



6-month FU



12- month FU



Clinical case #3: Male, 66 yrs old, Crush injury (right leg) and exposed metatarsal bones.

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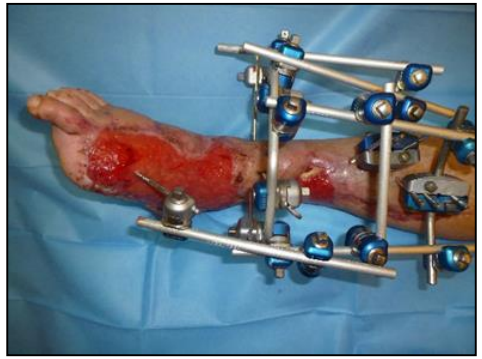

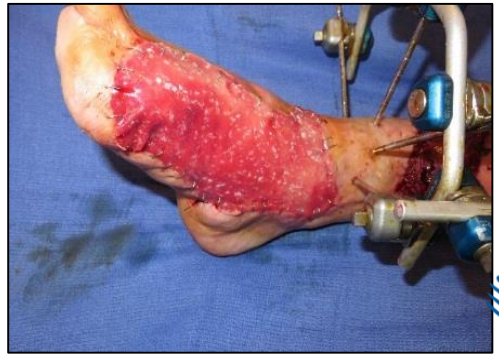

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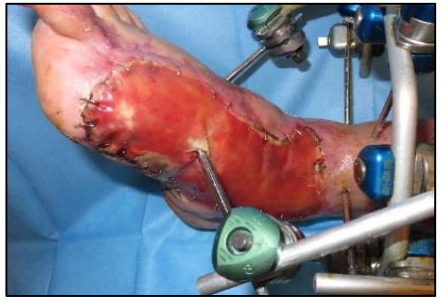
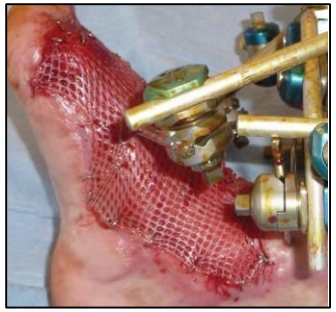
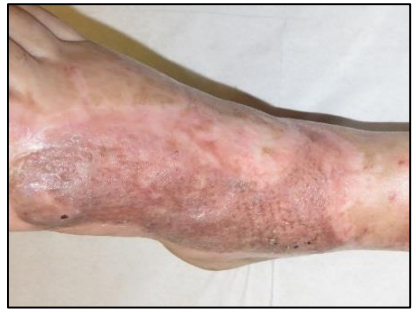


- Good trophicity in an area of friction and pressure
- Adapted to prolonged healing time to combine other treatment
- Wound recurrence prevention in shoes

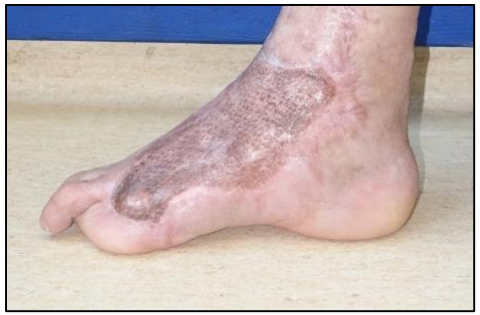
D21



6-month FU



12-month FU



Clinical case #4: Female, 62 yrs old, Tumor removal (melanoma) on right leg

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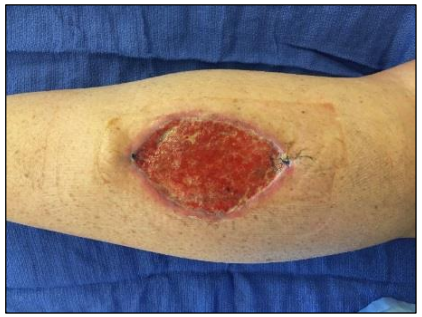

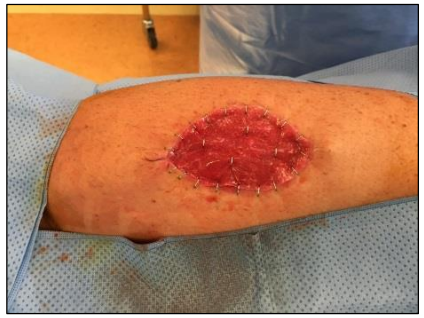

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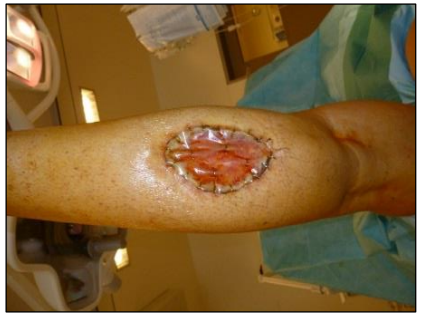
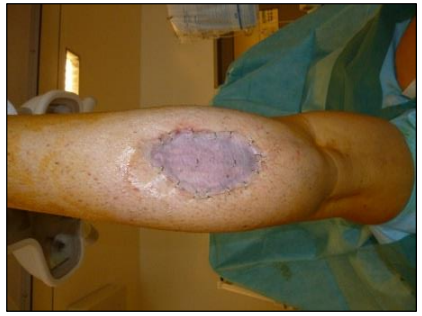
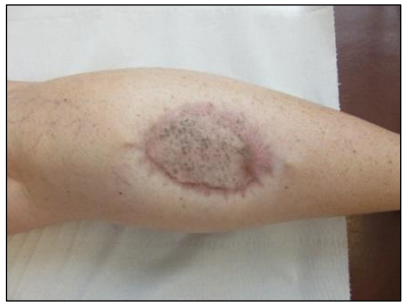


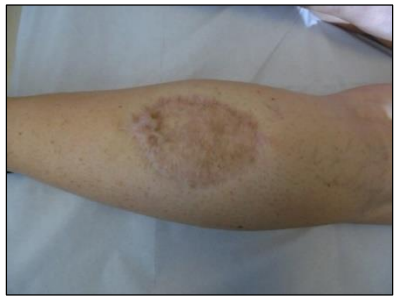


- Wise choice awaiting anatomopathologist results
- Facilitates monitoring of cancer recurrence
- *Ease of care for the elderly through faster mobilization*

6-month FU



12-month FU



Clinical case #5: Female, 68 yrs old, Necrotizing dermohypodermitis caused by an injury with a screwdriver (left hand)

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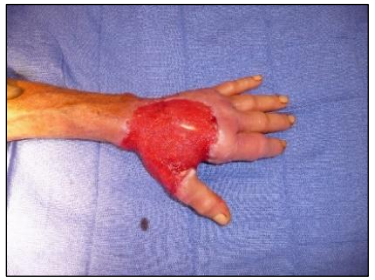
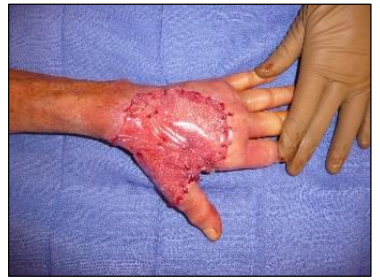
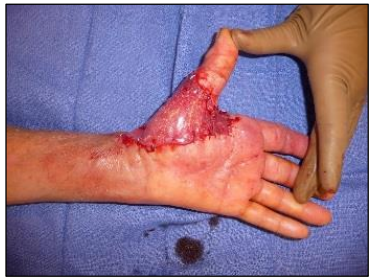
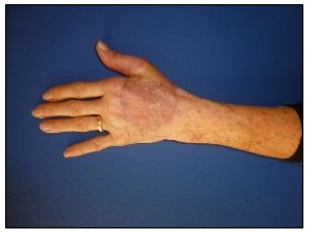


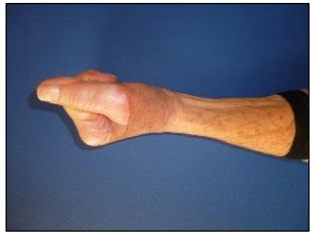


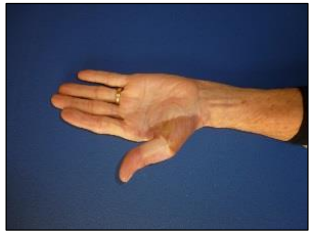
NEVELIA® implantation

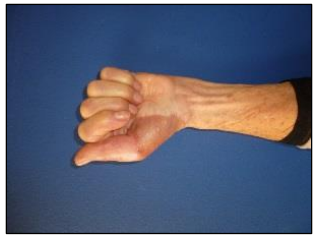


6-month FU

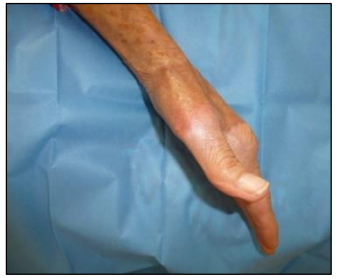


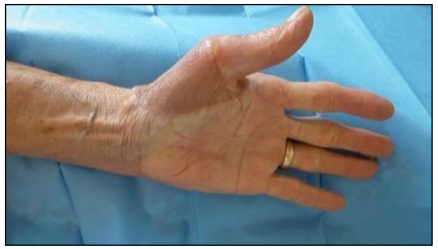






12 –month FU





- Adequate management & medical care in a mobile area